Standards for Kidney Transplant Services

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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 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; and
- Assuring management of health informatics, e-health and promoting innovation.

The Standards for Kidney Transplant Services aims to fulfil the following overarching Dubai Health Sector Strategy 2026:

- Promote the healthiest lifestyle for the people of Dubai.
- Pioneering prevention efforts against non-communicable diseases.
- 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.

ACKNOWLEDGMENT

The Health Policy and Standards Department (HPSD) developed this Standard in collaboration with 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

TABLE OF CONTENTS

ACKNOWLEDGMENT 3

EXECUTIVE SUMMARY 6

DEFINITIONS 8

ABBREVIATIONS 11

1. **BACKGROUND** 12
2. **SCOPE** 12
3. **PURPOSE** 13
4. **APPLICABILITY** 13
5. **STANDARD ONE:** REGISTRATION AND LICENSURE PROCEDURES 13
6. **STANDARD TWO:** HEALTH FACILITY REQUIREMENTS 15
7. **STANDARD THREE:** HEALTHCARE PROFESSIONALS REQUIREMENTS 16
8. **STANDARD FOUR:** CONSENT FOR ORGAN TRANSPLANT 21
9. **STANDARD FIVE:** MEDICATION REQUIREMENTS 23
10. **STANDARD SIX:** DIALYSIS UNITS REQUIREMENTS 24
11. **STANDARD SEVEN:** PRE-OPERATIVE ASSESSMENT AND EVALUATION OF DONOR AND RECEPIENT CANDIDATES 25
12. **STANDARD EIGHT:** POST-OPERATIVE MANAGEMENT OF TRANSPLANT RECEPIENT 25

REFERENCES 26

APPENDICES 28

APPENDIX 1: PRE-KIDNEY TRANSPLANT CHECK-LIST 28

APPENDIX 2: CHECK-LIST FOR KIDNEY TRANSPLANT CANDIDATES WORKUP 30

APPENDIX 3: EXCLUSION CRITERIA FOR DONATION IN LIVING-DONOR KIDNEY TRANSPLANTATION (LDKT) 32

APPENDIX 4: PRE-OPERATIVE ASSESSMENT AND EVALUATION OF DONOR CANDIDATES 35

APPENDIX 5: PRE-OPERATIVE ASSESSMENT AND EVALUATION OF RECIPIENT CANDIDATES 37

APPENDIX 6: PARAMETERS FOR MONITORING GRAFT FUNCTION RECOVERY AND CLINICAL SURVEILLANCE FOR EARLY SURGICAL COMPLICATIONS 41

APPENDIX 7: SURVEILLANCE FOR KIDNEY TRANSPLANT COMPLICATIONS AFTER HOSPITAL DISCHARGE 42

EXECUTIVE SUMMARY

Kidney transplantation is the removal of a kidney from a living or dead donor and transferring it into 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 DHA licensed hospitals are of the highest standards and aligned with current international best practices.

The document elaborates the licensing requirements of a hospital 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 requirement, assessment and evaluation of donor candidate and pre-operative assessment and evaluation of recipient candidate This standard is aligned with all the applicable UAE laws and legislations related to the subject.

This Standards shall align with the following:

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

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

DEFINITIONS

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.

Donation is 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.

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

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:

- Related;
- Genetically Related;
- 1st Degree Genetic Relative: Parent, Sibling, Offspring;
- 2nd Degree Genetic Relative, e.g. Grandparent, Grandchild, Aunt, Uncle, Niece, Nephew;

- Other than 1st and 2nd Degree Genetically Related, e.g. Cousin;
- Emotionally Related: Spouse (if not genetically related); In-laws, Adopted, Friend; or
- Unrelated or Non-Related: Not Genetically or Emotionally Related.

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 refers to a person who is authorized to make decision on behalf of the patient (In case the patient is incompetent). Next of kin may include relatives up to the forth degree. In case relatives up to the forth 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 Donation Unit (ODU) is a 24/7 operating unit within the hospital ICU responsible for all organ donation matters, run by the organ donation unit director and coordinator(s).

Organ Donation Unit Coordinator (ODUC): ICU nurse, Intensivist or other trained clinical staff assigned by the health facility management, responsible for ensuring that all organ and tissue donation process steps occurs as per protocol and all communications between the ODU, DHA and the National Center for Donation and Transplant (NCDT) are done on timely manner to facilitate organ donation and transplant.

Organ Transplant Unit (OTU) is an area in the hospital 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 (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.

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

ABBREVIATIONS

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
MOHAP	:	Ministry of Health and Prevention
ODU	:	Organ Donation Unit
ODUC	:	Organ Donation Unit Coordinator
OT	:	Operating Theatre
OTU	:	Organ Transplant Unit
RN	:	Registered Nurse
SOP	:	Standard Operating Procedure
UAE	:	United Arab Emirates

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, 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 DHA licensed hospitals.

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.

A donor kidney may come from a deceased or 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 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 the UAE Laws and Dubai regulations.

5.2. Hospitals opting to provide kidney transplant services shall apply to Health Regulation Sector (HRS) and comply with the DHA licensure and administrative requirements available on the DHA website https://www.dha.gov.ae.

5.3. Accreditation

5.3.1. The hospital shall be accredited as per the DHA Hospital accreditation policy, before the commencement of the kidney transplant service.

5.3.2. The hospital laboratory must be accredited as per the DHA Clinical Laboratory accreditation policy, before the commencement of kidney transplant service.

5.4. The hospital shall have Standard Operating Procedures (SOPs) related to the Kidney Transplant Service. The relevant staff shall be trained to abide by these SOPs.

5.5. The health facility should develop the following policies and procedure; but not limited to:

5.5.1. Patient acceptance criteria

5.5.2. Recipient selection criteria

5.5.3. Patient assessment and admission

5.5.4. ABO Compatibility verification and documentation for Organ Transplantation

5.5.5. Pre-Transplant work up process

5.5.6. Post-Transplant follow up protocol

5.5.7. Patient education and informed consent

5.5.8. Patient health record

5.5.9. Infection control measures and hazardous waste management

5.5.10. Incident reporting

5.5.11. Patient privacy

5.5.12. Medication management

5.5.13. Emergency action plan

5.5.14. Patient discharge/transfer.

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

5.6.1. Equipment maintenance services

5.6.2. Laundry services

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

5.6.4. Housekeeping services.

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

5.8. 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.

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

6.1. Kidney transplant services shall only be performed in DHA licensed Hospitals.

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

6.3. The hospital 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. Radiology

6.3.5. Hematology

6.3.6. Pathology Laboratory

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

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

6.3.7. Biochemistry Laboratory

6.3.8. Nephrology with hemodialysis unit (preferably with portable dialysis machines).

6.3.9. Intensive Care Unit (ICU).

6.4. The hospitals shall provide the following:

6.4.1. Minimum of two Operating Theatres (OTs).

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

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

6.6. The hospital design should provide assurance of patient and staff health and safety.

6.7. The hospital shall have appropriate equipment and trained healthcare professionals to manage critical and emergency cases.

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

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

7.1. A DHA licensed hospital providing kidney transplant services shall have the following DHA licensed healthcare professionals:

7.1.1. Consultant Renal Transplant Surgeon with a minimum of 1-year experience from a recognised kidney transplant center.

7.1.2. Consultant Nephrologist with a minimum of 1-year experience from a recognised kidney transplant center.

7.1.3. Registered Nurses (RNs) experienced and trained to care for patients during and after kidney transplant.

7.1.4. Kidney Transplant Coordinators, minimum of two (2) certified[2] (could be one of the above).

7.1.5. Dietician

7.1.6. Social Worker.

7.2. The following Healthcare Professionals could provide support to the above team, but not limited to:

7.2.1. Cardiologist

7.2.2. Intensivist

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

7.2.4. Radiologist

7.2.5. Radiographer

7.2.6. Psychiatrist/Clinical Psychologist

7.2.7. Clinical Pharmacist

7.2.8. Physiotherapist.

[2] Certified by organizations like UNOS or equivalent

7.3. Kidney Transplant Committee shall consist of that shall meet on a regular bases to ensure smooth operation of the OTU:

7.3.1. Consultant Renal Transplant Surgeon

7.3.2. Consultant Nephrologist

7.3.3. Kidney Transplant Coordinator

7.3.4. Registered Nurse Representative

7.3.5. Quality Coordinator

7.3.6. Cardiologist (optional)

7.3.7. Anaesthesiologist (optional)

7.3.8. Urologist (optional)

7.3.9. Psychiatrist (optional)

7.3.10. Legal Representative (optional).

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

7.4.1. Acts as liaison between the National Center and the hospital OTU.

7.4.2. Work closely with coordinator(s) of the National Center and the Organ Donation Unit Coordinator (ODUC) of the donor facilities to facilitate donation and subsequent transplant.

7.4.3. Ensure that all potential transplant recipients and living donors meet transplant or donation criteria.

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

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

7.4.6. Prepare a waiting list for the hospital OTU.

7.4.7. Report the names of all patients fit for transplantation (workup patients) to The National Center to include them in the national waiting list.

7.4.8. Co-ordinate with The National Center when there is Death by Neurological Criteria (DNC), in any of the hospitals and extend assistance, as needed.

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

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

7.4.11. Oversee post-transplant care of patients.

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

7.6. The responsibilities of the Kidney Transplant Committee are as follows:

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

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

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

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

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

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

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

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

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

7.7. 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 on regular intervals aligned with the DHA Clinical Privileging Policy.

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

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

8.1. For potential transplant recipients who are on the wait-list for a deceased donor kidney, the consent shall be signed before the procedure. Living Related donors shall sign the consent before the donor workup begins. Check-list for kidney transplant candidate's workup is elaborated in **Appendix 2.**

8.2. Kidney Transplant Surgery Consent shall include the following:

8.2.1. Potential psychosocial risks post-transplant.

8.2.2. Transplant centre's observed and expected one-year survival rate.

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.

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

8.3.1. Potential psychosocial risks of donation.

8.3.2. Alternative treatments for the transplant candidate.

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

8.4. When the brain death 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.

8.5. Before performing transplantation from a living donor, the following conditions should be fulfilled; exclusion criteria for donation in Living-Donor Kidney Transplantation (LDKT) are elaborated in- **Appendix 3.**

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

8.5.2. 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.

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

8.5.4. 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.

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

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

8.5.7. Relevant medical examination should be performed on the donor and recipient before the transplantation.

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

8.6.1. 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.

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

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

8.8. Ensure donor and recipient confidentiality at all times.

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. Other similar drugs categories.

9.1.2. Drugs for treating rejection episodes:

a. Methylprednisolone

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

c. Monoclonal Antibodies.

9.1.3. Solution for perfusing the organs.

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

10. STANDARD SIX: DIALYSIS UNITS REQUIREMENTS

10.1. Every Kidney Transplant Unit 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 RECEPIENT CANDIDATES

11.1. The Pre-operative assessment and evaluation of Donor Candidate is elaborated in **Appendix 4.**

11.2. The Pre-operative assessment and evaluation of Recipient Candidate is elaborated in **Appendix 5.**

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

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 6**.

12.2. The surveillance for kidney transplant complications after hospital discharge are elaborated in **Appendix 7**.

12.3. The immunosuppressive therapy for Kidney Transplant recipients shall be under the supervision of a specialist/consultant Most Responsible Physician (MRP).

12.4. In case of rapid worsening of kidney function (creatinine increase) the Protocol of Acute Rejection therapy shall be provided as per the current international best practice.

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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, 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 IodThe National Centervidone 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 CANDIDATES 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	
MICROBIOLOGY ASSESSMENT	- Urine culture (if residual diuresis present)	
	- 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)	
	- Infectivologist 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: EXCLUSION CRITERIA FOR DONATION IN LIVING-DONOR KIDNEY TRANSPLANTATION (LDKT)

1. Age younger than 18 years
2. Incompetence to provide an explicit informed consent to donation
3. Psychiatric disorders or psychological concerns related to donation
4. Evidence of some form of coercion to donation
5. Drug abuse
6. Malignant neoplasia
    - 6.1. Screening for malignant neoplasia is mandatory since it represents an absolute contraindication;
    - 6.2. Past history of melanoma, testis cancer, renal cancer, choriocarcinoma, leukaemia, lymphoma, monoclonal gammapathy, bronchial cancer or breast cancer are an absolute contraindication although considered cured;
    - 6.3. Past history of other malignant neoplasms with a negative follow-up for disease recurrence of at least 5 years may not represent an absolute contraindication;
    - 6.4. A past history low grade skin cancers (excluding melanoma) is not a contraindication.
7. Pregnancy
    - 7.1. Major respiratory disease
    - 7.2. Cardiovascular diseases (heart failure, coronary disease, valves disease, arrhythmia).
8. Diabetes mellitus
    - 8.1. Fasting plasma glucose ≥126 mg/dL (7.0 mmol/L)

8.2. 2-h plasma glucose ≥200 mg/dL (11.1 mmol/L) during an oral glucose tolerance test

8.3. A1C ≥6.5%.

9. Renal diseases or abnormal renal function:

9.1. Renal scintigraphy: a radioisotope clearance < 80 ml/min/1.73 m2

9.2. Proteinuria over 300 mg in 24 hours

9.3. Hematuria: in presence of either hematuria, proteinuria <300mg in 24hrs, anomalies in the urine sediments, it may be indicated a kidney biopsy to exclude an underlying nephropathy.

10. Nephrolithiasis:

10.1. A past history of nephrolithiasis is not a contraindication to donation if there are no stones in the kidney or urether, signs of urinary infection, or crystals in the urine sediment

10.2. A single, small (diameter <1.5cm), uncomplicated stone which can be removed at back-table may not be a contraindication to donation.

11. Systemic diseases with renal involvement

12. Thrombophilia

13. BMI over 35:

13.1. A BMI lower than 35 but higher than 30 is considered a relative contraindication and the donor candidate should be enrolled in a dietary program to target a BMI<30;

13.2. Dyslipidemia is considered a relative contraindication and becomes relevant if associated with other risk factors.

14. Active infections:

14.1. Recurrent pyelonephritis are an absolute contraindication;

14.2. Active tuberculosis is an absolute contraindication while a past history of adequately treated and cured infection is a relative contraindication; a prophylactic therapy with isoniazide may be indicated;

14.3. A past history of renal tuberculosis is an absolute contraindication;

14.4. Uncomplicated urinary tract infection (UTI) must be treated and urine sterility must be assessed before donation;

15. HBV, HCV, HIV infections

16. Arterial hypertension:

16.1. Arterial pressure values over 140/90 mmHg

16.2. Borderline arterial pressure values without therapy but associated with other risk factors (smoking, obesity, dyslipidemia, diabetes), borderline renal function or microalbuminuria

16.3. Pharmacological therapy

16.4. Presence of secondary organ damage.

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

1. Preliminary Evaluation

    1.1. Physiologic and medical history, family medical history, physical examination

    1.2. Performance status and nutritional status.

2. Laboratory Test

    2.1. Blood group

    2.2. Complete blood count

    2.3. Serum creatinine, blood urea nitrogen (BUN), Sodium, potassium, calcium, clorum, glucose, Cystin C

    2.4. Creatinine clearance with Glomerular Filtration Rate (GFR) measurement, at least 3 times

    2.5. Full urine test with urine sediment examination (at least 3 times), proteinuria in 24 hours

    2.6. Serum Liver Transaminases (AST, ALT), Gamma Glutamyl Transpeptidase (GGT), Alkaline Phosphatase (ALP), Lactate Dehydrogenase (LDH)

    2.7. Serum total and direct bilirubin

    2.8. Serum HDL and non-HDL Cholesterol, Triglyceride

    2.9. Plasma proteins levels and protein electrophoresis

    2.10. PT, PTT, Fibrinogen

        2.10.1. Fecal occult blood test.

    2.11. Microbiology Tests

2.12. Urine culture test (2 times)

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

2.14. HCV-RNA, HIV-RNA

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

2.16. Screening for syphilis (VDRL, TPHA)

2.17. MANTOUX (if required)

3. Immunologic Tests

3.1. HLA typing

3.2. Donor/Recipient Cross Match

4. Other Preliminary Examinations

4.1. ECG, echocardiography, cardiologic examination

4.2. Chest x-ray

4.3. Abdominal Ultrasound

4.4. Psychological evaluation.

5. Second-Level Investigations

5.1. Specific examinations for previously suspected or diagnosed pathologies (chest CT scan, mammography and US, gynecologic examination)

5.2. Angio-CT scan or Angio-MR imaging

5.3. Uro-CT scan or perfusion urography

5.4. Renal scintigraphy.

APPENDIX 5: 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

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

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

12.4.3. HCV-RNA, HIV-RNA

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

12.4.5. Screening for syphilis (VDRL, TPHA)

12.4.6. 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 6: PARAMETERS FOR MONITORING GRAFT FUNCTION RECOVERY AND CLINICAL SURVEILLANCE FOR EARLY SURGICAL COMPLICATIONS

Diuresis	Daily urine output, creatinine clearance, urine sediment, urinecolture
Body temperature	In presence of fever, the following investigations are indicated: • Full blood count, • Renal function panel, • Full urine test, • Urinecolture, • Hemocolture, • Microbiological colture of the abdominal drainage liquid and wound secretion, • US scan, • Chest x-ray
Abdominal drainage tube	Daily output; measurement of creatinine, LDH, glucose; microbiological colture
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, leucopiastrinopenia, 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 time a week until POD 10 or when clinically indicated.

APPENDIX 7: SURVEILLANCE FOR KIDNEY TRANSPLANT COMPLICATIONS AFTER HOSPITAL DISCHARGE

Cardiovascular diseases	• Follow up cardiologic examination and tests as appropriate
Infectious complications	• Urinecolture 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 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