STANDARDS FOR VASCULARIZED COMPOSITE ALLOGRAFT (LIMB) TRANSPLANT SERVICES

Version (1)

Issue date: 27/05/2024

Effective date: 27/07/2024

Health Policies and Standards Department

Health Regulation Sector (2024)

ACKNOWLEDGMENT

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

Health Regulation Sector

Dubai Health Authority

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INTRODUCTION

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

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

The Standard for Vascularized Composite Allograft (limb)Transplant Services aims to fulfill the following overarching Dubai Health Sector Strategy 2026:

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

EXECUTIVE SUMMARY

Vascularized composite allograft (VCA) (Limb) transplantation is the removal of a whole or part of a limb or limbs from a deceased or brain-dead donor and transplanting them onto an eligible recipient with non-reconstructable limb loss. This document is developed to ensure that VCA (limb) services provided in DHA licensed health facilities are of the highest standards and aligned with current international best practices.

The document elaborates the licensing requirements of a hospital aiming to provide VCA (limb) transplant service, the health facility requirements, the healthcare professional requirements, the donor family and recipient consent for organ transplant, assessment and evaluation of donors, pre-operative assessment, and evaluation of recipients for candidacy, medication requirements, and criteria for life-long care of recipients of VCA (limb) transplant. This standard is aligned with all the applicable United Arab Emirates (UAE) laws and legislations related to the subject.

This Standards shall align with the following:

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

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

DEFINITIONS

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

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

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

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

Health Facility is a facility licensed by DHA to provide medical services to individuals, including areas of prevention, treatment, and convalescence owned and managed by natural or corporate body.

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

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.

Limb Vascularized Composite Allograft for the purpose of this document includes upper limb vascularized composite allografts. Upper limb includes any group of vascularized body parts from the upper limb.

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

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

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

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 occur as per protocol and all communications between the ODU, and the National Center for Donation and Transplant (NCDT) are done on timely manner to facilitate organ donation and transplant.

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

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

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

ABBREVIATIONS

ADM	:	Abductor Digiti Minimi
ALP	:	Alkaline Phosphatase
ALT	:	Alanine Transaminase
APB	:	Abductor Pollicis Brevis
ASLOT	:	Antistreptolysin O Titer
AST	:	Aspartate Aminotransferase
ATG	:	Anti-Thymocyte Globulin
AZA	:	Azathioprine
BAVTNV	:	Bone-2 Arteries-2 Veins-Tendons-Nerves-Remaining Veins
BID	:	Bis In Die (Twice Per Day)
BKV	:	B.K. Virus
BMI	:	Body Mass Index
CAD	:	Chronic Allograft Dysfunction
CBC	:	Complete Blood Count
CCSU	:	Critical Care Support Unit
CCSUC	:	Critical Care Support Unit Coordinator
CMP	:	Complete Metabolic Panel
CNI	:	Calcineurin Inhibitors
CMV	:	Cytomegalovirus
CPK	:	Creatine Phosphokinase

CT	:	Computed Tomography
DASH	:	Disability of Arm, Shoulder, and Hand
DHA	:	Dubai Health Authority
DM	:	Dubai Municipality
DNA	:	Deoxyribonucleic Acid
DNC	:	Death by Neurological Criteria
DSA	:	Donor-Specific Alloantibody
EBV	:	Epstein-Barr Virus
ECG	:	Electrocardiogram
ECU	:	Extensor Carpi Ulnaris
EDC	:	Extensor Digitorum Communis
EGDS	:	Esophagogastroduodenoscopy
EI	:	Extensor Indicis
EMG	:	Electromyography
ESR	:	Erythrocyte Sedimentation Rate
FCU	:	Flexor Carpi Ulnaris
FDI	:	First Dorsal Interosseus
FPL	:	Flexor Pollicis Longus
GGT	:	Gamma Glutamyl Transpeptidase
GFR	:	Glomerular Filtration Rate
HBV	:	Hepatitis B Virus

HCV	:	Hepatitis C Virus
HFG	:	Health Facility Guidelines
HIV	:	Human Immunodeficiency Virus
HLA	:	Human Leukocyte Antigens
HRS	:	Health Regulation Sector
HTK	:	Histidine–Tryptophan–Ketoglutarate
HTLV	:	Human T-Lymphotropic Virus
ICU	:	Intensive Care Unit
IgG	:	Immunoglobulin G
IgM	:	Immunoglobulin M
INR	:	International Normalised Ratio
IPV	:	Inactivated Polio Vaccine
LC-DC	:	Limited Contact – Dynamic Compression
LDH	:	Lactate Dehydrogenase
MMF	:	Mycophenolate Mofetil
MMR	:	Measles, Mumps and Rubella
MMT	:	Manual Muscle Testing
MOHAP	:	Ministry of Health and Prevention
MP	:	Metacarpophalangeal
MRI	:	Magnetic Resonance Imaging
m-TOR	:	Mammalian Target of Rapamycin

NCV	:	Nerve Conduction Studies
NEO	:	Neuroticism, Extraversion, Openness Test
OD	:	Once Daily
OT	:	Operating Theatre
OTU	:	Organ Transplant Unit
PPT	:	Pain Pressure Threshold
PO	:	Per Os (By Mouth)
POD	:	Postoperative Day
PRA	:	Panel Reactive Antibody
ROM	:	Range of Motion
RN	:	Registered Nurse
RNA	:	Ribonucleic Acid
STAT	:	Statim (Immediately)
SOP	:	Standard Operating Procedure
TDM	:	Therapeutic Drug Monitoring
TENS	:	Transcutaneous Electrical Nerve Stimulation
TPHA	:	Treponema Pallidum Hemagglutination
US	:	Ultrasound
UAE	:	United Arab Emirates
UW	:	University of Wisconsin
VCA	:	Vascularized Composite Allograft

VDRL	:	Venereal Disease Research Laboratory
WHO	:	World Health Organization

1. BACKGROUND

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

In September 2020, The National Center to Regulate Human Organs and Tissues Transplantation1 was established. The National Center aims to unify the national efforts in the field of transplantation of human organs and tissues, regulate and coordinate organ transplant surgeries across the country.

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

VCA transplantation is the transplantation of a composite tissue that may include skin, muscle, bone, and nerves that requires blood flow to function after the transplant. A donor VCA may come from a deceased cardiac death or brain-dead donor.

2. SCOPE

2.1. VCA (limb) services in 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 services in DHA licensed health facilities.

4. APPLICABILITY

4.1. DHA licensed healthcare professionals and health facilities providing VCA (limb) services.

5. STANDARD ONE: REGISTRATION AND LICENSURE PROCEDURES

5.1. All health facilities providing VCA (limb) Transplant Services shall adhere to the United Arab Emirates (UAE) Laws and Dubai regulations.

5.2. Health facilities opting to provide VCA (limb) Transplant Services shall comply with the DHA licensure and administrative procedures available on the DHA website https://www.dha.gov.ae.

5.3. Licensed health facilities opting to add VCA (limb) Transplant Services shall inform Health Regulation Sector (HRS) and submit an application to HRS to obtain permission to provide the required service.

5.4. Accreditation

5.4.1. The hospital shall be accredited as per the DHA Hospital accreditation policy before the commencement of VCA (limb) transplant service.

5.4.2. The hospital laboratory must be accredited as per the DHA Clinical Laboratory accreditation policy before the commencement of VCA (limb)

transplant service.

5.5. The hospital shall employ a DHA licensed consultant surgeon with training and experience in VAC transplant service as described in this document. The hospital must demonstrate that the consultant transplant surgeon meets the requirements set forth in these standards in their application to HRS.

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

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

5.7.1. Patient Continuity of care

5.7.2. The health facility's own patient acceptance criteria and exclusion criteria for the VCA (limb) transplant waitlist, taking into account the results of the work-up assessment for the potential transplant candidate, as elaborated in **Appendix 1**.

5.7.3. Patient education and Informed consent, including the provision of donor risk criteria present.

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

5.7.5. Candidate pre-operative assessment and evaluation, including the requirements listed in **Appendix 2**.

5.7.6. ABO Compatibility verification and documentation for Organ Transplantation, conducted by the transplant surgeon and another healthcare professional, in accordance with the requirements listed in **Appendix 2**.

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

5.7.8. Pre-transplant workup process immediately prior to transplant surgery, including the requirements listed in **Appendix 4**.

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

5.7.10. Post-transplant follow-up protocol, including the requirements listed in **Appendices 5** (monitoring)**, 6** (outpatient rehabilitation)**, and 7** (non-physiotherapy testing after discharge)**.**

5.7.11. Patient health record must be maintained and demonstrate that all policies and procedures were followed.

5.7.12. Infection control measures, including post-transplant surveillance testing detailed in **Appendices 5 and 7**, and hazardous waste management.

5.7.13. Patient privacy.

5.7.14. Medication management.

5.7.15. Emergency action plan.

5.7.16. Patient discharge/transfer.

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

5.8.1. Transfer of critical/complicated cases when required.

5.8.2. Patient discharge.

5.8.3. Clinical laboratory services.

5.8.4. Equipment maintenance services.

5.8.5. Laundry services.

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

5.8.7. Housekeeping services.

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

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

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

5.12. The health facility shall allocate sufficient operating and recover room resources, intensive care resources, surgical beds, and personnel to the VCA (limb) Transplant Services.

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

6.1. VCA (limb) Transplant Services shall only be performed in DHA licensed health facilities with Role Delineation Level 5 to 6, or general hospitals with more than 100 beds.

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

6.3. The health facility shall have an Organ Transplant Unit (OTU) to ensure integrated and seamless transplant services, including VCA (limb) Transplant services.

6.4. Health facilities providing VCA (limb) Transplant services shall have the following services:

6.4.1. Plastic and Reconstructive surgery.

6.4.2. Orthopedics.

6.4.3. Cardiology.

6.4.4. Pulmonology.

6.4.5. Nephrology.

6.4.6. Hematology.

6.4.7. Pathology Laboratory.

6.5. All routine investigations necessary for patients both before and after the transplantation must be available.

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

6.7. Biochemistry laboratory.

6.8. Physiotherapy.

6.9. Quality Management.

6.10. Health facilities opting to perform VCA (limb) Transplant services must have fully equipped Intensive Care Unit (ICU) capabilities with ventilators and hemodynamic monitoring equipment on-site to perform necessary patient resuscitation.

6.11. The hospital shall provide the following:

6.11.1. Minimum of two Operating Theatres (OT).

6.11.2. Minimum of two rooms for the management of post-transplant patients.

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

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

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

6.15. 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.

6.16. The health facility 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 VCA (limb) transplant services shall have a team of healthcare professionals to ensure the smooth functioning of the service to ensure patient continuity of care.

7.2. There must be DHA licensed Consultant Vascular Surgeons/Hand Surgeon/ Neurosurgeon/Orthopedic Surgeon/Plastic Surgeon with training and experience in heart transplant and privileged to do so aligned with the DHA Privileging Policy.

7.3. The consultant Vascular surgeon (team lead) is responsible for ensuring the operation and compliance of VCA (limb) transplant services with requirements set forth in this document. The consultant surgeon will be the point of contact specialist for planning, coordinating, and executing the transplant process, including:

7.3.1. Acceptance of the screened donor per established criteria.

7.3.2. Preparation of the donor team for limb recovery.

7.3.3. Activation of the recipient team and OR for surgery.

7.3.4. Choregraphing the entire surgical procedure and ensuring the successful

performance of the surgery.

7.3.5. Ensuring post-operative management of the patient, including therapeutic and rehabilitative aspects.

7.3.6. Taking overall responsibility and accountability for each VCA procedure.

7.4. The consultant VCA (limb) surgeon must meet the following conditions:

7.4.1. The surgeon must have performed:

a. At least two (2) years of consecutive, independent practice of limb surgery.

b. A minimum number of limb procedures as the primary surgeon according to the table below, including pre-operative assessments and post-operative care for a minimum of ninety (90) days after surgery.

Type of Procedure	Minimum Number of Procedures
Bone	20
Nerve	20
Tendon	20
Skin or Wound Problems	14
Contracture or Joint Stiffness	10
Tumour	10
Microsurgical Procedures Free flaps	10
Non-surgical Management	6
Replantation or Transplant	5

c. These procedures must be documented in a log that includes the date of the procedure, the role of the surgeon in the procedure, and the medical record number or other unique identifier that can be verified.

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

d. Observed at least two (2) multi-organ procurements, documented in a log including date of procurement and a unique identifier that can be verified. This log must be signed by an individual in a supervisory position from the hospital where the experience was gained.

7.5. A DHA licensed health facility providing VCA (limb) transplant services shall have the following DHA licensed healthcare professionals to support the physician mentioned above:

7.5.1. **Anaesthesiologist** with experience in transplantation.

7.5.2. **VCA (Limb) Transplant Coordinator** to work with patients and their families to coordinate care, beginning with the evaluation for transplantation and continuing through and after transplantation. The coordinator shall be a registered nurse or other licensed clinician with experience in transplantation and replantation.

7.5.3. **Registered Nurses (RNs)** with experience in transplantation and replantation. The post-transplant ICU must have nurses trained in free-flap monitoring.

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

7.5.5. **Clinical Pharmacist** to provide comprehensive medication management to transplant candidates and recipients.

7.5.6. **Psychiatrist** to conduct pre-transplant psychological assessment to gain insight into how the candidate might do during and after the transplant event, as post-transplant compliance with the recommendations of the transplant team is vital to the success of the procedure.

7.5.7. **Occupational Therapist** to manage rehabilitation regimen including 3-6 hours of supervised therapy 5 days a week during the first 3-6 months following the procedure or longer as needed due to the nature of the transplant. The Hand Therapist must have training in management of replants or tendon injuries.

7.5.8. **Histopathologist** with experience in tissue rejection and transplant pathology, with some dermatopathology expertise.

7.5.9. **Clinical Social Worker** to coordinate psychosocial needs of transplant candidates, recipients, and their families and advocate for the transplant candidate/recipient.

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

7.5.11. **Head of the Critical Care Support Unit and Organ Donation Unit Coordinator** who is responsible for defining hospital deceased organ donation policy, assessing deceased organ donor potential, and measuring

KPIs for organ donation as defined by published DHA standards and reporting them to HRS on a monthly basis.

7.6. VCA (limb) transplant services shall collaborate with medical experts in these fields; including but not limited to:

7.6.1. Anaesthesiology (with paediatric transplant experience, as appropriate).

7.6.2. Histocompatibility and immunogenetics.

7.6.3. Immunology.

7.6.4. Infectious Disease.

7.6.5. Pathology.

7.6.6. Physical therapy and rehabilitation medicine.

7.6.7. Radiology.

7.6.8. Orthopaedics.

7.6.9. Plastic Reconstructive Surgery.

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

7.6.11. Cardiology, as appropriate.

7.6.12. Hepatology, as appropriate.

7.6.13. Nephrology, including dialysis capability, as appropriate.

7.6.14. Paediatrics, if applicable.

7.6.15. Psychologist.

7.6.16. Social Worker.

7.7. VCA (Limb) Transplant Coordinators shall be assigned in each OTU providing VCA (limb) transplant services, with the following responsibilities:

7.7.1. Act as liaison between the Organ Donation and Transplantation team of DHA (where applicable) the National Center and the hospital OTU.

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

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

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

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

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

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

7.7.8. Provide to HRS and The National Center the names of all patients determined to be suitable for VCA (limb) transplant following a completed transplant workup. These shall be included on the national waitlist.

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

7.7.10. Continually update all relevant information with the National Center regarding a candidate's status on the waitlist.

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

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

7.8. A DHA licensed health facility providing VCA (limb) transplant services shall have a VCA (Limb) Transplant Committee to ensure efficiency and safe transplant services. The VCA (Limb) Transplant Committee shall meet on a regular basis to ensure smooth operation of the OTU and consist of the following:

7.8.1. Consultant VCA (limb) Surgeon (lead).

7.8.2. VCA (limb) Transplant Coordinator.

7.8.3. Psychiatrist/Clinical Psychologist.

7.8.4. Social Worker.

7.8.5. Registered Nurse Representative.

7.8.6. Quality Coordinator.

7.8.7. Physiotherapist.

7.8.8. Consultant Orthopaedic Surgeon (Optional).

7.8.9. Consultant Plastic Reconstructive Surgeon (optional).

7.8.10. Cardiologist (optional).

7.8.11. Legal Representative (optional).

7.9. A DHA licensed health facility providing paediatric VCA (limb) transplant services shall have a VCA (Limb) Transplant Committee to ensure efficiency and safe transplant services. The VCA (Limb) Transplant Committee shall consist of the same members as the adult VCA (Limb) Transplant Committee, except the following positions must have paediatric specializations:

7.9.1. Child-centered Occupational Therapist.

7.9.2. Paediatric Psychiatrist/Clinical Psychologist.

7.10. The responsibilities of the VCA (Limb) Transplant Committee are as follows:

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

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

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

7.10.4. Make clinical decisions as to which potential candidates are suitable for

wait listing and which candidates should be rejected, based on criteria set forth by The National Center.

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

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

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

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

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

7.10.10. Develop and regularly update Policies and Procedures related to VCA (Limb) Transplant Service to ensure efficient and safe provision of services.

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

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

8. **STANDARD FOUR:** INFORMED CONSENT FOR VCA (LIMB) TRANSPLANT

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

8.2. VCA (Limb) Surgery Consent shall include the following:

8.2.1. Testing requirements for procedures performed before surgery.

8.2.2. Use of medications after transplant, including the need for immunosuppressive medications for the lifetime of the graft.

8.2.3. Potential psychosocial risks post-transplant.

8.2.4. Post-transplant rehabilitation and physiotherapy requirements, testing, and biopsy schedule

8.2.5. Transparency around the time and effort that will be required for post-operative care, and the need to strive for complete compliance with all aspects of rehabilitation.

8.2.6. Surgical risks, including risk of death, risks of anaesthesia, risks of rejection, risks of immunosuppressive drugs, risks of graft failure, and risk of cancer development.

a. For paediatric patients and their proxies providing consent, a special emphasis on the long-term immunosuppressive risks and potential impact on overall lifespan compared to alternative treatments, if they are not already on immunosuppressive medications due to a previous

solid organ transplant.

b. Involve family and a donor advocate in the consent process to highlight unique issues such as mismatched or impaired limb growth in paediatric patients receiving above-elbow transplants, which include the growth plates in the elbow joint.

8.2.7. OTU's observed and expected one-year survival rate, beginning one year after the hospital's first VCA (limb) transplant.

8.2.8. Alternative treatments for the prospective transplant candidate, which include but are not limited to passive prosthesis, body-powered prosthesis, electrically powered prosthesis, hybrid prosthesis and activity-specific prosthesis.

8.2.9. Reiterate the rigorous demands of rehabilitation.

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

8.2.11. Donor with the risk of disease transmission shall not be included as potential transplant donors.

8.2.12. Educate and prepare recipients for the receiving of new fingerprints.

8.3. Before performing deceased donor recovery, the following conditions must be met:

8.3.1. It is not permissible to remove an organ unless the donor's wish is conclusively confirmed and documented on the deceased donation consent

form, signed by the deceased donor's relatives in accordance with Federal Decree Law No. (25) of 2023.

8.3.2. When 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. Brain death confirmation must be documented in the donor's medical record as well as documentation of the consent for donation obtained.

8.3.3. A cosmetic prosthesis must be fitted on the donor following limb retrieval to enable funeral viewing and preserving body integrity.

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

8.4. Always ensure donor and recipient confidentiality.

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

9. **STANDARD FIVE:** MEDICATION REQUIREMENTS

9.1. Health facilities providing VCA (limb) transplant services should ensure the in-house availability of the following drugs, but not limited to:

9.1.1. Immunosuppressive drugs:

a. Campath 1H (Alemtuzumab) (as needed).

b. Tacrolimus (Prograf).

c. Prednisolone (Solumedrol).

d. Other similar drugs categories.

9.1.2. Drugs for treating rejection episodes:

a. Methylprednisolone

b. Rapamune (Sirolimus, Rapamycin).

c. Cell Cept (Mycophenolate mofetil).

d. Temovate (Clobetasol propionate).

e. Cutivate (Fluticasone propionate).

f. Anti-Thymocyte Globulin (ATG).

g. Monoclonal Antibodies.

9.1.3. Solution for perfusing the organs such as University of Wisconsin solution or HTK solution.

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

10. STANDARD SIX: PRE-OP ASSESSMENT AND EVALUATION OF DONOR & CANDIDATE

10.1. A detailed medical history with respect to any previous disease, drug intake and prior surgical procedures shall be taken of any patient indicated for VCA (limb).

10.2. In the case of a paediatric candidate, individuals who have previously received a solid organ transplant and are already on immunosuppressive medications may be better suited for VCA (limb), as the risk-benefit ratio of adding immunosuppression to a patient for a non-lifesaving transplant where alternate treatments exist is evident.

10.3. Known contraindications shall be considered (and their absence) and noted in the health records which may include the following:

10.3.1. For bilateral transplant-only hospitals: unilateral amputees with no evidence of significant functional, social, or financial impairment because of their amputation.

10.3.2. Congenital amputees.

10.4. The pre-operative assessment and evaluation of Recipient Candidate is elaborated in **Appendix 2**.

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

10.6. The pre-transplant checklist for immediately prior to transplant is elaborated in **Appendix 4**.

11. STANDARD SEVEN: INTRA-OPERATIVE CARE

11.1. Two surgical teams working simultaneously will help reduce the cold ischemic time.

11.1.1. The recipient team prepares the recipient for transplant. The team begins surgery with dissection of the amputated stump and identification and marking of blood vessels, tendons, and nerves.

11.1.2. The donor team which procured the limb works on the back table to prepare the donor limb for transplant.

11.1.3. Similar to hand replantation, the order of BAVTNV is usually followed, and immunosuppression is initiated per protocol.

11.1.4. Induction agents (Thymoglobulin, Basiliximab, alemtuzumab etc.) and methylprednisolone are begun prior to restoring the blood flow through the graft.

11.2. The timing of procurement and recipient procedures and the need for two surgical teams is critical for success of the VCA (limb) transplant. The transplant coordinator is responsible this timing and ultimately for a smooth procedure.

11.3. For paediatric patients, a protocol should be established in advance for managing intra-operative volumes to ensure optimized haemodynamics, while minimizing the use and risks of extensive blood products.

12. **STANDARD EIGHT:** POST-OPERATIVE CARE

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

12.2. The outpatient rehabilitation regiment post-transplant is elaborated in **Appendix 6**.

12.3. Post-operative testing (non-physiotherapy) for the VCA (limb) transplant recipient is elaborated in **Appendix 7**.

12.4. Long-term post-discharge management of the VCA (limb) transplant recipient is elaborated in **Appendix 8**.

12.5. The immunosuppressive therapy for VCA (limb) Transplant recipients is elaborated in **Appendix 9**.

12.6. In case of rapid worsening of limb graft function the Protocol of Acute Rejection

therapy is elaborated in **Appendix 10**.

12.7. The protocols of Chronic Allograft Dysfunction (CAD) management are elaborated in **Appendix 11**.

13. STANDARD NINE: KEY PERFORMANCE INDICATORS

13.1. The Key Performance Indicators (KPIs) are elaborated in **Appendix 12**.

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

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

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

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

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APPENDICES

APPENDIX 1: CHECK-LIST FOR VCA (LIMB) POTENTIAL TRANSPLANT CANDIDATE WORKUP

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

CHECK-LIST FOR VCA POTENTIAL TRANSPLANT CANDIDATE WORKUP		CHECK
PRELIMINARY EVALUATION	• Medical history, family medical history, physical examination, including weight/BMI. • Detailed evaluation of the underlying need for transplantation. • Performance status and nutritional status. • Nerve conduction studies and needle electromyography. • Anthropometric measurements. • Estimate BMI in amputees without prosthetics for eGFR calculations.	
LABORATORY TEST	• Blood group tested on two separate occasions, with different collection times, prior to addition to wait-list.	
	• Complete blood count.	
	• Blood gas test.	
	• 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	• Urine culture (if residual diuresis present).	

ASSESSMENT	• Hepatitis Panel: ○ Hepatitis A antibody (HAAb). ○ Hepatitis B core antibody (HBcAb). ○ Hepatitis B surface antibody (HBsAb). ○ Hepatitis B surface antigen (HBsAg). ○ Hepatitis C antibody.	
	• Hepatitis Quantitative Testing: ○ HBV – DNA. ○ HCV – RNA.	
	• HIV Testing: ○ HIV – RNA.	
	• Syphilis Antibody Testing: ○ VDRL. ○ TPHA.	
	• Serologies: ○ CMV (IgM, IgG). ○ EBV (IgM, IgG). ○ Toxoplasmosis (IgM, IgG). ○ HTLV I - II (IgM, IgG).	
	• Tuberculosis Test (if required): ○ Mantoux tuberculin skin test.	
	• Infectious Disease Consultant Evaluation (if indicated).	
	• Serology (IgG, IgM) HTLV I-II.	
	• Infectious Disease consult.	
IMMUNOLOGIC ASSESSMENT	• HLA typing.	
	• Panel reactive antibodies (PRA).	
	• Immunization Records Review. • All patients should receive the following vaccinations prior to transplant: ○ Td or Tdap. ○ IPV. ○ Hepatitis B. ○ Meningococcal (conjugate). ○ Pneumococcal (conjugate and/or polysaccharide).	

	○ Hib. ○ Influenza (administered annually). ○ MMR. ○ Varicella.	
CARDIOLOGIC ASSESSMENT	Cardiologic examination.	
	ECG.	
	Echocardiography.	
	Exercise Cardiac Stress Test.	
	Myocardial Perfusion scintigraphy (if indicated).	
IMAGING	Chest-abdomen-pelvis CT scan.	
	Screening imaging studies to assess stump integrity, vascular patency, tendon, and nerve anatomy.	
ENDOSCOPIC ASSESSMENT	EGDS with HP test.	
	Colonoscopy.	
OTHERS	(For women) Gynecologic examination, PAP TEST Mammography and US scan.	
	(For men) Urologic examination with prostate US scan.	
	Dental examination with orthopantomogram.	
	Fundus exam.	
	Dermatologic examination.	
	Psychological evaluation (see reference below).	
	Anesthesiologist evaluation.	

REFERENCE PSYCHOSOCIAL SCREENING FOR VCA (LIMB) POTENTIAL TRANSPLANT CANDIDATE

1. All VCA (limb) transplant candidates will undergo a thorough psychiatric consultation prior to transplantation. This comprehensive evaluation of emotional and cognitive preparedness for transplant and decision-making capacity includes:

   1.1. Psychologic impact of amputation.

1.2. Coping and adjustment with limb loss.

1.3. History of prosthetic use and compliance with rehabilitation and medication.

1.4. Motivation for limb transplantation.

1.5. Emotional and cognitive preparedness for limb transplantation, including body image adaptation, level of realistic expectations regarding post-transplant outcomes, anticipated comfort with the transplanted limb.

1.6. Personality organization/risk of regression.

1.7. History of medication compliance/substance abuse.

1.8. Social support system/family structure.

1.9. For combat veterans, additional areas should include the manner of amputation and psycho-behavioural issues like post-traumatic stress disorder, depression, or anxiety.

2. The VCA (limb) transplant candidate and their spouse or caretaker will meet with a transplant social worker for assessment of the social system available to support the patient during transplantation and the post-transplant rehabilitation period.
3. Psychologic testing is to be repeated yearly post-transplant.
4. A comprehensive psychiatric interview for VCA (limb) transplantation employs structured instruments to gather clinical data on aspects of the patient's character and behaviour, previously shown to be relevant to limb transplantation, in accordance with the table below.
5. While there is no right or wrong answer to these types of questions, this information will be used in the assessment, selection, and ultimate preparation of potential hand transplant candidates.

Questionnaire	Purpose	General Description
Perlin Self-Mastery Scale	To assess sense of mastery over the amputation/limb loss.	These questionnaires provide information on coping abilities, ability to self-regulate emotional distress, ability to tolerate expected stresses of transplantation, compliance with follow-up, and ability to form a working relationship with the hand transplant team. They also assess emotions regarding: • body image or negative self-perceptions of appearance or functional abilities relating to body image; • personal satisfaction regarding body appearance and self-perception; • personal relationships with relatives, significant others, or friends; • belief/confidence in performance of a certain task/s and personal judgment of what a subject can do/not do with his/her skills/capabilities.
Rosenberg Self Esteem Scale	To evaluate self-esteem.	
Coping Responses Inventory	To determine coping with stress of the amputation and attempt to predict how the subject will cope with the transplanted hand.	
Sherwood's Self Concept Inventory	To estimate how the amputation has impacted subject's sense of self- identity and how transplant could modify it.	
NEO Personality Scale short form	To test subject personality traits and characteristics.	
SF-36 and Disability of Arm, Shoulder, and Hand (DASH)	To establish overall quality of life before and after hand transplant.	

APPENDIX 2: PRE-OPERATIVE ASSESSMENT AND EVALUATION OF TRANSPLANT RECIPIENT

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

PRE-OPERATIVE ASSESSMENT OF VCA (LIMB) TRANSPLANT RECIPIENT		**CHECK**
PRELIMINARY EVALUATION	• Physiologic and medical history.	
	• Patient and Family medical history, including: ○ Mechanism of injury/death; ○ Vascular access placement; ○ History of limb dysfunction/paralysis.	
	• Physical examination, including but not limited to: ○ Range of motion (ROM) of the available joints; ○ Manual muscle testing (MMT) of available muscles; ○ Response of the residual forearm musculature to electrical muscle stimulation; ○ Documentation of pain and sensitivity complaints; ○ Scar quality; ○ Level of amputation; ○ Sensation; ○ Edema; ○ Skin and soft tissue integrity; ○ Circumference of the forearms at varying levels as well as length of the forearms; ○ A Carroll test, using the prothesis to evaluate preoperative functional level; ○ DASH (Disabilities of the Arm, Shoulder, and Hand Instrument questionnaire), completed by the patient.	
	• Performance status and nutritional status.	
	• Physical attributes: ○ Skin tone, scars, tattoos, distinguishing marks, mechanism of injury, sex/gender, body habitus, height, weight, limb length, laterality (if unilateral).	

	• Donor/Recipient Matching:
	  ○ Age match within 10 years if adult, or 2 years of paediatric recipient.
	  ○ Bone size within 15% of the recipient.	

LABORATORY TESTING	• ABO blood typing (perform two separate tests at different times, **prior** to addition to wait-list.	
	• Complete blood count (CBC).	
	• Serum Liver Transaminases (AST, ALT), Gamma Glutamyl Transpeptidase (GGT), Alkaline Phosphatase (ALP), Lactate Dehydrogenase (LDH).	
	• Serum total and direct bilirubin.	
	• Full lipid panel dosage.	
	• Complete Metabolic Panel (CMP) (including electrolytes, renal panel, Na, K, Cl, CO2, Cr, BUN, Ca, PO4).	
	• Full urine test with urine sediment examination (if residual diuresis is present).	
	• Urine culture test (2 times).	
	• Plasma proteins levels and protein electrophoresis.	
	• Serum HDL and non-HDL Cholesterol, Triglyceride.	
	• Complete coagulation function panel (PT or INR, PTT, Fibrinogen).	
	• Fecal occult blood test.	
	• CPK, CPK-MB.	
	• ESR, ASLOT.	
	• Plasma proteins levels and protein electrophoresis.	

MICROBIOLOGY ASSESSMENT AND INFECTIOUS DISEASE TESTING	• Hepatitis Panel:
	  ○ Hepatitis A antibody (HAAb).
	  ○ Hepatitis B core antibody (HBcAb).
	  ○ Hepatitis B surface antibody (HBsAb).
	  ○ Hepatitis B surface antigen (HBsAg).
	  ○ Hepatitis C antibody.	

	• Hepatitis Quantitative Testing: ○ HBV – DNA.	

	○ HCV – RNA.	
	• HIV Testing: ○ HIV – RNA.	
	• Syphilis Antibody Testing: ○ VDRL. ○ TPHA.	
	• Serologies: ○ CMV (IgM, IgG). ○ EBV (IgM, IgG). ○ Toxoplasmosis (IgM, IgG). ○ HTLV I - II (IgM, IgG).	
	• Tuberculosis Test: ○ Mantoux tuberculin skin test.	
	• Infectious Disease Consultant Evaluation (if indicated).	
CARDIOVASCULAR ASSESSMENT	• Cardiologic examination.	
	• Electrocardiogram.	
	• Echocardiography.	
	• Exercise cardiac stress test.	
	• Myocardial Perfusion scintigraphy (if indicated).	
	• Chest X-ray.	
	• Patients with positive screening tests should be referred to cardiologist for further evaluation. Intervention may allow for future listing.	
IMAGING ASSESSMENT	• MRI of abdomen/pelvis.	
	• CT scan (Chest/Abdomen/Pelvis).	
OTHER TESTING	• Nerve conduction studies (NCV).	
	• Needle electromyography (Needle EMG).	
	• EGDS Test with HP.	
	• Colonoscopy.	
	• Color Doppler of the iliac-femoral axis and supraaortic vessels.	
	• Ophthalmic exam, including fundus exam.	
	• Uro-CT scan or perfusion urography.	

	• Cystometry.	
	• Dermatologic exam.	
	• Psychological exam.	
	• Anesthesiologist evaluation.	
	• Dental Examination, (including orthopantomogram.	
GENDER-SPECIFIC ONCOLOGICAL STUDIES	• Digital Prostate Exam, PSA Testing (for males).	
	• PAP Test, Mammogram (for females).	
IMMUNOLOGIC EVALUATION	• HLA Typing.	
	• Donor and Recipient cross match.	
	• Immunization Records Review or Catch-up. • All patients should receive the following vaccinations prior to transplant: ○ Td or Tdap. ○ IPV. ○ Hepatitis B. ○ Meningococcal (conjugate). ○ Pneumococcal (conjugate and/or polysaccharide). ○ Hib. ○ Influenza (administered annually). ○ MMR (live). ○ Varicella (live). • Live vaccines must be completed at least six weeks before transplantation. Yearly influenza immunization is indicated for all immunosuppressed individuals.	

2. DETAILS ABOUT THE PHYSICAL EXAMINATION

2.1. Regarding the physical examination, for hand transplant, the testing of strength of the forearm, wrist and finger muscles helps the surgeon understand the status of residual muscles that will power the transplanted hand.

2.2. The patient is instructed in the use of electrical muscle stimulation as well as

isometric exercise to aid in pre-operative strengthening of these muscles.

3. DETAILS ABOUT NERVE CONDUCTION STUDIES (NCV)

3.1. The NCV documents how well the motor and sensory nerves function in the stump by measuring motor conduction in the median, ulnar, and radial nerves, and sensation in the superficial radial, lateral antebrachial cutaneous, and medial antebrachial cutaneous.

3.2. The goal of the NCV is to determine the functional status of:

3.2.1. Motor nerves in the stump.

3.2.2. Sensory nerves in the stump.

3.2.3. Muscles in the stump.

Figure 1: Upper arm, Ulnar Nerve NCV

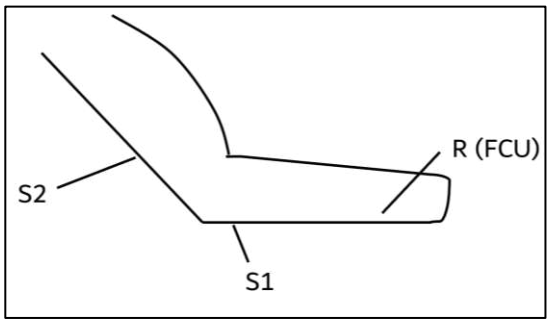
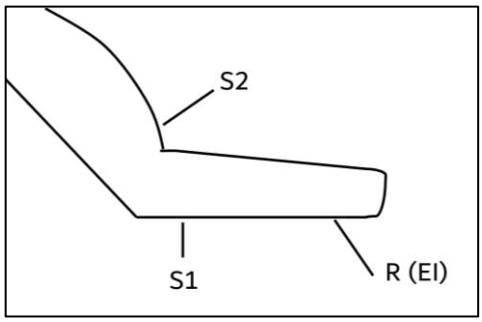


Figure 2: Upper arm, Radial Nerve NCV



3.2.4. Motor conduction studies read the median, ulnar, and radial nerves across the elbow and the stump, measured by standard methods:

Nerve	Process
Motor Conduction Studies	
Median	• Place recoding electrode over the flexor pollicis longus (FPL) ○ Surface electrodes are usually sufficient, but if the anatomical location of muscle is altered due to past injury and subsequent

	amputation, it may be necessary to use needle recording electrode, preferably concentric needle. • Stimulate at the elbow medial to the biceps tendon and at the medial upper arm (see figure 1). • Distal latency is a measure of motor conduction in the nerve in the forearm stump.
Ulnar	• Place recording electrode over the flexor carpi ulnaris (FCU) • Stimulate the ulnar nerve below and above the elbow.
Radial	• Place recording electrode over the extensor indicis (EI), if present; otherwise, extensor carpi ulnaris (ECU) or extensor digitorum communis (EDC) may be used. • Stimulate at the dorsal forearm and proximally along the lateral border of the distal (see figure 2).
Sensory Conduction Studies	
Superficial radial	• Place the recording electrode over the radial aspect of the forearm. • Stimulate proximally with a needle electrode at the lateral aspect of the distal upper arm between biceps and brachioradialis.
Lateral antebrachial cutaneous	• Place recording electrode over the radial volar aspect of proximal forearm. • Stimulate at or above the elbow along the course of the nerve.
Medial antebrachial cutaneous	• Place recording electrode over the medial volar aspect of proximal forearm. • Stimulate at or above the elbow along the course of the nerve.

4. DETAILS ABOUT NEEDLE ELECTROMYOGRAPHY (Needle EMG)

4.1. The goal of the Needle EMG is to identify intact muscles in the stump and document their innervation status.

4.2. A concentric needle electrode is inserted into the muscle, and the patient is asked to contract the target muscle volitionally, meaning the patient imagines movement of fingers and/or the wrist.

4.2.1. By moving the needle around, the location of each muscle can be

determined.

4.2.2. The resulting pattern provides clues as to the quantity of motor units that can be volitionally activated, thereby identifying muscles that are good candidates for attaching to the tendons of the transplant.

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

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

CHECK-LIST FOR POTENTIAL VCA (LIMB) DONOR WORKUP		CHECK
PRELIMINARY EVALUATION	Consent of family specific to VCA (limb), due to the outwardly apparent donation of limb.	
	Patient social history (including smoking, alcohol, drug use).	
	Patient and Family medical history, including: • Mechanism of injury/death. • Vascular access placement. Donor should not have A-lines or dialysis access ports in the limbs. • History of limb dysfunction/paralysis.	
	Physical examination., including but not limited to: • Range of motion (ROM) of the available joints. • Response of the residual forearm musculature to electrical muscle stimulation. • Documentation of pain and sensitivity complaints. • Edema. • Skin and soft tissue integrity. • Circumference of the forearms at varying levels as well as length of the forearms (anthropometric measurements).	
	Physical attributes: • Skin tone, scars, tattoos, distinguishing marks, mechanism of injury, sex/gender, body habitus, height, weight, limb length, laterality (if unilateral, palm span). • Skin swatches can be provided to donor hospitals to match skin tone of recipients.	
	Donor/Recipient Matching • Age match within ten (10) years if adult, or with two (2) years if paediatric recipient. • Bone size within 15% of the recipient.	

	• Sex of the donor. • Skin colour matching.	
LABORATORY TESTING	ABO blood typing (perform two separate tests at different times, **prior** to addition to wait-list).	
	Complete blood count (CBC).	
	Serum Liver Transaminases (AST, ALT), Gamma Glutamyl Transpeptidase (GGT), Alkaline Phosphatase (ALP), Lactate Dehydrogenase (LDH).	
	Serum total and direct bilirubin.	
	Complete Metabolic Panel (CMP) (including electrolytes, renal panel, Na, K, Cl, CO_2, Cr, BUN, Ca, PO_4).	
MICROBIOLOGY ASSESSMENT AND INFECTIOUS DISEASE TESTING	Hepatitis Panel: • Hepatitis A antibody (HAAb). • Hepatitis B core antibody (HBcAb). • Hepatitis B surface antibody (HBsAb). • Hepatitis B surface antigen (HBsAg). • Hepatitis C antibody.	
	Hepatitis Quantitative Testing: • HBV – DNA. • HCV – RNA.	
	HIV Testing: • HIV – RNA.	
	Syphilis Antibody Testing: • VDRL. • TPHA.	
	Serologies: • CMV (IgM, IgG). • EBV (IgM, IgG). • Toxoplasmosis (IgM, IgG). • HTLV I - II (IgM, IgG).	
	Tuberculosis Test (if needed): • Mantoux tuberculin skin test.	
	Infectious Disease Consultant Evaluation (if indicated).	
IMAGING ASSESSMENT	MRI of abdomen/pelvis.	

	CT scan (Chest/Abdomen/Pelvis).	

APPENDIX 4: PRE-VCA (LIMB) TRANSPLANT CHECK-LIST

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

PRE-VCA TRANSPLANT CHECK-LIST	
RECIPIENT CANDIDATE CHECKLIST	**CHECK**
Select an appropriate recipient candidate according to ○ Donor/recipient Cross Match. ○ Donor/recipient clinical/demographic match. ○ Medical urgency, time on waiting list.	
Call the selected recipient candidate and admit to hospital.	
Confirm recipient identity and basic medical information, including: ○ Recipient unique identifier (i.e., Medical Record Number). ○ Recipient blood type.	
Review pre-limb transplant workup (see **Appendix 1**).	
Order Urgent chest x-ray.	
Order Urgent ECG.	
Order Urgent blood exams (full blood count, renal function, blood gas test, coagulation function).	
Request for Anesthesiologist re-evaluation.	
Alert ICU if postoperative ICU admission is expected.	
Order four packed red blood cells units (for unilateral) ten units (for bilateral).	
Activate the operating room.	
Obtain written informed consent for limb transplant from recipient.	
Prepare the patient for surgery.	
Administer immunosuppressive induction therapy.	
Prescribe antibiotic prophylaxis.	
If donor/recipient CMV mismatch, prescribe postoperative CMV prophylaxis.	
VCA GRAFT CHECKLIST	**CHECK**
Confirm donor identity and donor/recipient matching, including blood type.	

Review donor demographic and clinical characteristics.	
Review organ procurement surgical report.	
Review pathologic examination and serologies.	
Explant the limb at the desired level under tourniquet control (transradial, transhumeral or supracondylar amputation).	
Perfuse the limb with 1L heparinized UW or HTK solution.	
Evaluate graft vascular perfusion at back-table (on table angiogram if needed).	
Place the graft in static cold storage (triple bagged) for transportation.	
Prepare the graft for implantation at recipient OR back-table (dissect all structures and tag for identification of tendons, vessels, and nerves).	
VCA TRANSPLANT CHECKLIST	**CHECK**
Prior to induction of anesthesia - confirm with the patient their identity, planned procedure, informed consent, any reported allergies.	
Mark site of transplantation.	
Review pre-transplant CT angiogram.	
Check availability of hand tables, microsurgical sets, and LC-DC plates with pneumatic drills.	
Prepare 1 L Saline 0.9% with povidone iodine 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).	
Prep and drape the surgical field.	
Before skin incision, call for Timeout for WHO Surgical Safety Checklist.	
Conduct verification required upon hand/extremity receipt, prior to anastomosis, with the intended recipient in the room, of: • Donor and recipient identification. • Organ type. • Blood type and compatibility of donor and recipient. • Correct donor extremity is identified for the correct side of recipient.	

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

1. Health facility must maintain documentation in the patient's medical record to support that all elements of the protocol were followed.
2. Monitor for rejection.
    2.1. Diagnosing rejection.
        2.1.1. Clinical signs of skin rejection are nonspecific and may include:
            a. Erythematous maculopapular rash.
            b. Edema.
            c. Erythema.
            d. Hair loss.
            e. Desquamation at the fingers.
        2.1.2. Pathological evidence of acute rejection: lymphocyte infiltrates.
        2.1.3. Pathological evidence of chronic rejection: Vessel intimal hyperplasia.
    2.2. Patient protocol.
        2.2.1. Weekly skin biopsies for the first month post-transplant.
        2.2.2. Weekly laboratory testing for the first month post-transplant.
            f. Kidney function.
            g. Immunosuppression drug concentrations.
            h. Complete blood count.
3. Neurophysiological Evaluation for Hand Transplantation.
    3.1. Nerve conduction studies (NCV) and Needle Electromyography (Needle EMG) after

surgery.

3.1.1. Serial studies of NCV and Needle EMG help determine the progress of reinnervation post-transplant.

3.1.2. For motor conduction studies of median, ulnar, and radial nerves, the abductor pollicis brevis (APB), abductor digiti minimi/first dorsal interosseous (ADM/ FDI) and extensor indicis (EI), respectively are used for recording.

3.1.3. Sensory conduction studies may consist of recording of mixed nerve action potentials over the wrist, by midpalmar (orthodromic) stimulation of median and ulnar nerves and recording of sensory potentials over the digital branches (with ring electrodes) by antidromic stimulation at the wrist.

3.1.4. These studies may be done at 6-month intervals or more often if feasible.

4. The health facility shall report to DHA and the National Center, within 72 hours of the health facility being made aware, if any of the following may have occurred:

4.1. A transplant of an incorrect organ into an organ recipient.

4.2. A transplant of an organ into the incorrect recipient.

APPENDIX 6 : OUTPATIENT REHABILITATION REGIMEN AFTER VCA (LIMB) TRANSPLANTATION

1. Health facility must maintain documentation in the patient's medical record to support that all elements of the protocol were followed.
2. Patient protocol.
    2.1. Continue to follow up with transplant center every 2-3 months during the first year post-transplant and 6-12 months thereafter.
    2.2. Continue intensive physiotherapy protocol on daily basis during the first year post-transplant.
    2.3. Serial evaluation of reinnervation at 6-month intervals, or more often if feasible.
3. Graft outcomes assessment for upper limb transplants.
    3.1. Grip strength and pinch test.
    3.2. Two-point discrimination test.
    3.3. Hot and cold sensation.
    3.4. Basic command questions.
        3.4.1. Is the patient able to make a fist?
        3.4.2. Can the patient comb their hair?
        3.4.3. Can the patient open a door?
        3.4.4. Can the patient write on a piece of paper?
        3.4.5. Can the patient hold a cup?
4. Post-Operative Therapy for Hand Transplantation.

4.1. Immediately following surgery, the surgeon and therapist should know the exact level of nerve anastomosis; type of bone fixation and stability; and details of type of tendon repairs. These are all essential in the planning of splinting and therapy.

4.2. Therapy and splinting goals should include:

4.2.1. Functional hand positioning of intrinsic plus position of the fingers with the thumb abducted palmarly and radially.

4.2.2. Pain and edema control using transcutaneous electrical nerve stimulation (TENS), elevation (level dependent on arterial versus venous compromise) and gentle controlled exercise.

4.2.3. Appropriate exercises to encourage tendon gliding while protecting repairs is important as well as full ROM in all joints that can be safely mobilized.

4.2.4. Education of patient and family members in the performance of all exercises, as well as the importance of keeping the limb warm and avoiding smoking and caffeine.

4.2.5. Protection of the finger extensors for as long as needed to prevent any lag.

4.2.6. Through week 12 post-transplant, or longer: Prevent full metacarpophalangeal (MP) extension to aid development of mild tightness in the intrinsics which will in turn prevent future clawing. The patient, nurses, residents, etc. must all be educated to this goal.

4.2.7. Education of patient in sensory precautions, including awareness of potential damage to the transplant limb from hot, cold, or sharp objects.

4.3. Formal Therapy and Bracing for Hand Transplantation:

4.3.1. Approximately three (3) to five (5) days posttransplant, use the crane extension outrigger splint.

a. This splint positions the hand appropriately and allows for initiation of exercise. Within this splint:

(i) The wrist is positioned in slight extension.

(ii) The metacarpophalangeal joints in fifty (50) to seventy (70) degrees of flexion.

(iii) The interphalangeal joints held at zero (0) degrees by light dynamic extension.

(iv) The thumb is held in a balance between radial and palmar abduction, again in light dynamics.

b. The patient is given instructions for hourly gentle mass active flexion of the fingers with passive extension by the rubber band traction.

4.3.2. On a graduated basis posttransplant, exercises are added.

a. These exercises should include:

(i) Protected passive range of motion.

(ii) Place and hold exercises.

(iii) Gentle individual finger and thumb flexion without resistance (relax rubber band tension).

(iv) Forearm pronation/supination positioning initially and then active ROM.

(v) Shoulder and elbow ROM.

(vi) Wrist ROM in an assisted fashion may be initiated relatively early as dictated by bony fixation.

b. It is essential the MPs be supported in flexion whenever the crane outrigger is removed for any reason.

c. Exercise repetitions and frequency as well as the use of electrical stimulation will be dependent on the type of repairs, tissue response to healing, muscle fatigue and the time post-op.

d. The hand therapist must observe closely for signs of rejection, noting that it is common for the patient to feel significant fatigue initially while adjusting to immunosuppressive medications:

(i) Rash-like redness around hair follicles.

(ii) Unexplained swelling.

(iii) Change in temperature or colour of the transplanted part.

4.3.3. Formal scar management begins after suture removal. Circumferentially compressive materials must be avoided until four (4) weeks post-op.

4.3.4. At approximately three (3) weeks post-operatively:

a. A hand based anti-claw splint is fabricated and worn during tenodesis exercises for fifteen (15) minutes, three (3) times per day. The crane extension outrigger is continued at all other times.

(i) If there is any finger extension lag at this point, an outrigger can be added to the anti-claw splint to provide light support to the extensors.

(ii) This tenodesis exercise prepares the patient for light functional activities in the near future.

(iii) During the time the anti-claw splint is worn the patient may also begin gentle mid-range wrist ROM with light assistance as needed.

(iv) There will be a gradual progression in the use of the anti-claw splint over time with the crane outrigger continuing to be used at night as long as the fractures and/or extensor tendons need support.

(v) The anti-claw splint is used if there is any tendency to claw, which may be many months. Wehbe-Hunter tendon gliding exercises need to be modified as the patient should not allow the MPs to come to full extension. These exercises should be performed within the anti-claw splint.

4.3.5. Desensitization is added to the treatment plan over time.

a. TENS is very helpful with the treatment of nerve sensitivity and electrodes are placed over the nerve distribution of the major nerve, causing discomfort.

b. Manual desensitization techniques are incorporated into the treatment plan as well, providing a transition into sensory re-education when the appropriate time comes.

4.3.6. At four (4) to five (5) weeks post-op, the patient should progress their active exercise effort level.

a. Gentle progressive blocking exercises may be added if there is limited tendon gliding. This progression aids tendon healing strength.

b. Light functional activities within the anti-claw splint are included.

c. Depending on the level of healing and adhesion of tendons, electrical muscle stimulation to aid tendon gliding may be added.

d. The patient must begin visually inspecting the transplanted hand as the length of time spent in the anti-claw splint increases.

e. Patient awareness of anaesthetic skin safety precautions becomes more important as light functional activities are increased.

f. This is a time to consider the need for possible assistive devices to aid the patient's increasing level of independence.

g. As functional level increases, hand dominance issues and future work requirements should be addressed.

4.3.7. At approximately eight (8) weeks:

a. Light strengthening is initiated with the level of resistance dependent on the amount of tendon glide available, i.e., if the tendons demonstrate significant adhesions, exercises can be more aggressive.

b. Start with strengthening of the finger flexors and wrist extensors and then advance as tolerated.

4.3.8. From eight (8) weeks forward:

a. The hand should be used for more functional activities, progressive resistive exercises, and work simulation tasks.

b. The care team should evaluate the need for other splints to correct any residual contracture.

(i) A dynamic finger extension pan may be used to aid strengthening of lumbricals as innervation occurs.

(ii) A dynamic wrist flexion/extension splint or pronation/supination splint may be used to gain full motion and/or to give resistance for strengthening these motions.

5. Evaluation of Progress after Discharge for Hand Transplantation:

Range of Motion	Followed closely through goniometric measurements, and measurement of distance from fingertips to distal palmar crease.
	Initial measurements are taken within the crane outrigger, and then within the anti-claw splint. • These modifications are documented. • These modifications are used to compare measurements post-splint discontinuation.

	Total active ROM measurements should be collected. • Note that results can vary from day to day, or even repetition to repetition, based upon things such as hand or room temperature or a lack of complete motor learning. • The goal is a trend of overall improvement.
Strength	Measuring for improvements in finger flexor strength, which translates into increasing finger flexion ROM.
	Assessments include quality of movement and endurance.
	The ability to overcome gravity as wrist ROM improves.
	As healing progresses, muscles are tested through standard MMT.
	As nerve regeneration occurs, may see subtle intrinsic muscle function such as trace contraction of lumbricals or thumb adduction.
	After first observation of intrinsic muscle contraction, all intrinsic muscles should be tested using standard MMT.
	After twelve (12) weeks post-op, grip and pinch strength can be tested using the Jamar dynamometer and pinch meter.
Sensation	Usually the most delayed of the post-op measures.
	Should be tracked initially with documentation of progression of Tinel's sign.
	Vibration testing, Semmes-Weinstein monofilaments and static/moving two-point discrimination are also valuable tests as nerve regeneration occurs.
	The Moberg pick up test should be administered when function allows.
Function	Standard test of function is the Carroll test. Patient demonstrates functional abilities by: • Picking up and placing wooden blocks; • Pouring from a pitcher; • Picking up very small ball bearings; • Other similar activities.
	Maintain a record of improvements in functional capabilities by a standard Activities of Daily Living checklist.
	Videotaping specific functions to observe changes in speed and quality of those functions is also valuable.
Swelling	Volume is recorded on a regular basis for baseline information.

APPENDIX 7: POST-OPERATIVE TESTS (NON-PHYSIOTHERAPY) FOR VCA (LIMB) TRANSPLANT RECIPIENT AFTER DISCHARGE

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

TEST	DESCRIPTION	PURPOSE
CBC, Differential count, clotting profile, serum electrolytes, glucose, liver function, renal function, tacrolimus drug trough levels.	Estimated volume of blood: 1tsp to 1 tbsp. • POD 1 – 30: Once every day. • POD 31 – 60: Once every 2 days. • POD 61 – 90: Once every 6 days. • Post-op Week 13 - 52: Once every 2 weeks. • Thereafter whenever necessary, during rejection episodes and at yearly follow up.	To assess patient blood counts, glucose and electrolyte levels, overall liver and kidney function, and levels of the drug tacrolimus.
Hemoglobin A1c.	Estimated volume of blood: 1tsp. • POD 1 – 30: Once every two weeks. • POD 30 – 90: Once per month. • Thereafter whenever necessary, during rejection episodes and at yearly follow up.	To assess patient ability to control glucose levels.
Chimerism, Crossmatch, Mixed Lymphocyte Assay, Cylex Assay, Antidonor Antibodies.	Estimated volume of blood: 1tsp to 1 tbsp. • POD 1 – 30: Once every two weeks. • POD 30 – 90: Once every month. • Thereafter whenever necessary, during rejection episodes and at yearly follow up.	To establish how the recipient is responding to the transplanted hand.
CMV and EBV PCR testing.	Estimated volume of blood: 1tsp to 1 tbsp. • POD 1 - 30: Once every two weeks. • Month 2 and Month 3 post-op.	To test the presence or reactivation of viruses like cytomegalovirus (CMV) or Epstein Barr virus (EBV)

	• Thereafter whenever necessary (e.g., CMV infection) and at yearly follow up.	in the patient.
Skin Biopsies.	• POD 1 – 30: Once every week. • POD 30 – 1 year post-op: Monthly. • 1-2 years post-op: Once every 3 months. • Once every year thereafter at follow up visits or when rejection in the hand is observed.	To monitor rejection in the transplanted hand/forearm. If rejection is detected, appropriate measures will be instituted to control and treat such episodes and prevent further episodes from occurring.
X-Ray of Hand/Forearm, Ultrasound, Electromyography (EMG), Nerve Conduction Velocity (NCV).	• Monthly for months 1 – 12. • Yearly post-op.	To assess the healing of bone and condition of blood vessels in the transplanted hand.
Angiography and CT Angiography.	• POD 30. • Yearly post-op.	To evaluate the regrowth of nerves and the response of muscles to nerve stimulation.

APPENDIX 8: LONG-TERM MANAGEMENT FOR VCA (LIMB) TRANSPLANT RECIPIENT POST-DISCHARGE

1. Health facility must maintain documentation in the patient's medical record to support that all elements of the protocol were followed.
2. The transplant team should use the Hand Transplantation Comprehensive Outcome Scoring System for the International Hand Transplant Registry to serially evaluate the outcomes for the transplant recipient, demonstrated below.
3. After one year post-transplant, the VCA (limb) transplant patient will be discharged from the host city to continue physiotherapy care locally.
    1.1. A local therapist must be prearranged to ensure continuity of care, ideally the therapist who saw the patient at the time of his or her amputation or someone with hand therapy certification.
    1.2. The therapist should meet with the patient preoperatively and visit the patient during the initial three (3) months treatment time to gain familiarity with the overall process.
    1.3. The local therapist can determine appropriate frequency of treatment with an expectation of decreasing frequency in the months to come.
    1.4. The local therapist must communicate regularly with the transplant team on the patient's progress.
2. The patient must visit the transplant surgeon for progress evaluation after six (6) months post-transplant, one (1) year post-transplant, and annually thereafter. During these visits:
    2.1. Updated measurements will be taken.
    2.2. Videotaping of the patient and their functional capabilities should be included.
3. Long-term expectations for the patient and their functional capabilities should include:

3.1. A hand that functions well as a non-dominant hand.

3.2. Limited fine motor control of the transplanted limb.

3.3. Limited functional sensation of the transplanted limb.

3.4. Some continued small gains in sensation and strength up to five (5) years post-operatively.

REFERENCE: THE HAND TRANSPLANTATION COMPREHENSIVE OUTCOME, THE INTERNATIONAL REGISTRY SCORE SYSTEM

The scoring system considers the following characteristics:

Appearance	15 points
Sensibility	20 points
Movement	20 points
Psychological and Social Acceptance	15 points
Daily Activities and Work Status	15 points
Patient Satisfaction and General Well-Being	15 points
Total	100 points

Outcomes are assessed using the following rubric:

0-30 Points	Poor
31-60 Points	Fair
61-80 Points	Good
81+ points	Excellent

Appearance (Max 15 Points)		
Characteristic	**Results**	**Points**
Skin Colour and Vascularization	Normal	3
	Abnormal	0
Skin Texture	Normal	3
	Abnormal	0
Hair Growth	Normal	3

	Diminished	1.5
	Abnormal	0
Nail Growth	Normal	3
	Diminished	1.5
	Abnormal	0
(Only for Monolateral Transplant) Matching with Contralateral Hand (size, colour, texture)	Excellent	3
	Good	2
	Fair	0.5
	Poor	0
(Only for bilateral transplant) Matching with Upper Limb/Body	Excellent	3
	Good	2
	Fair	0.5
	Poor	0
	TOTAL	

Sensibility (Max 20 Points)		
Characteristic	**Results**	**Points**
Tactile Sensation (Semmes-Weinstein Monofilament Testing)		
Median Nerve	Green (1.65-2.83)	3 points
	Blue (3.22-3.61)	3 points
	Purple (3.84-4.31)	2 points
	Red (4.56)	1 point
	Red (6.65)	0 points
Ulnar Nerve	Green (1.65-2.83)	3 points
	Blue (3.22-3.61)	3 points
	Purple (3.84-4.31)	2 points
	Red (4.56)	1 point
	Red (6.65)	0 points
Protective Sensation (hot-cold-pain)		
	Yes (median-ulnar)	5 points
	Yes (median)	2 points
	Yes (ulnar)	1 point
	Yes (radial)	1 point
	No	0 points

Discriminative Sensation (Highest scale as modified by Dellon et al)		
Median Nerve	S2PD – grade S4 (2-6mm)	3 points
	S2PD – grade S3+ (7-12mm)	2.5 points
	S2PD – grade S3 (>15mm)	1.5 points
	S2PD – grade S2 (none)	0 points
Ulnar Nerve	S2PD – grade S4 (2-6mm)	3 points
	S2PD – grade S3+ (7-12mm)	2.5 points
	S2PD – grade S3 (>15mm)	1.5 points
	S2PD – grade S2 (none)	0 points
Sweating		
	Normal	2 points
	Abnormal	0 points
	TOTAL	

Movement (Max 20 Points)		
Characteristic	**Results**	**Points**
Active Range of Motion		
Forearm (combined prono-supination)	>150^0	2 points
	>120^0	1 point
	>90^0	0.5 points
Wrist (combined flexion/extension)	>90^0	2 points
	>45^0	1 point
	>25^0	0.5 points
Thumb and long fingers (total digital ROM of contralateral or normal hand -%)	>50%	2 points
	>25%	1 point
	>10%	0.5 points
Strength (Jamar Dynamometer)		
Grip	>10kgs	2 points
	>5kgs	1 point
	>2.5kgs	0.5 points
Pinch	>2kgs	2 points
	>1kgs	1 point
	>0.5kgs	0.5 points
Intrinsic Muscle Activity		

	Clinically useful	6 points
	EMG detectable	3 points
	None	0 points
Cortical Reintegration of the Hand (based on a positive functional MRI)		
	Yes	4 points
	No	0 points
	TOTAL	

Psychological and Social Acceptance (Max 20 Points)		
Characteristic	**Results**	**Points**
Social Behaviour		
	Holding/shaking hands	1 point
	Feeling well in a group	1 point
	Overcoming sense of embarrassment	1 point
	Sense of being accepted	1 point
	Ability to create new relationships	1 point
	Being able to overcome handicap	1 point
	Satisfactory global social acceptance	1 point
Affectiveness		
	Caressing	1 point
	Hugging	1 point
	Touching	1 point
	Sense of intimacy with partner	1 point
	Satisfactory global affect	1 point
Body Image		
	Sensation of having a complete body	1 point
	Self confidence in personal appearance	1 point
	Use of jewellery, watch, etc on hand/s	1 point
	TOTAL	

Daily Activities and Work Status (Max 15 Points)		
Characteristic	**Results**	**Points**
Activities of Daily Life		
	Driving/riding a bicycle	1 point

	Combing hair/personal hygiene/shaving	1 point
	Grasping glass	1 point
	Pouring water from bottle	1 point
	Using cutlery/chopsticks	1 point
	Brush teeth	1 point
	Holding hands	1 point
	Writing	1 point
	Symmetrical use of hands	1 point
Work Status		
	Employed	6 points
	Unemployed	0 point
	TOTAL	

Patient Satisfaction and General Well-Being (Max 15 Points)		
Characteristic	**Results**	**Points**
Patient Satisfaction		
	Very Satisfied	5 points
	Satisfied	3 points
	Unsatisfied	0 points
Well-Being		
	Physically and mentally healthy	5 points
	On pharmacological treatment for side effects	0 point
	Permanent side effects/pathologies from drugs	-5 points
Quality of Life (subjective assessment)		
	Improved a lot	5 points
	Improved	3 points
	Same	0 points
	Worsened	-3 points
	Worsened a lot	-5 points
	TOTAL	

TOTAL SCORE		
Category	Score	Max Score
Appearance		15 points

Sensibility		20 points
Movement		20 points
Psychological and Social Acceptance		15 points
Daily Activities and Work Status		15 points
Patient Satisfaction and General Well-Being		15 points
Total		100 points

APPENDIX 9: IMMUNOSUPPRESSIVE THERAPY FOR VCA (LIMB) TRANSPLANT RECIPIENTS

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

POD 0	Induction therapy: • Basiliximab (IL2 receptor antagonist): 20mg i.v. Maintenance therapy: • Methylprednisolone 250 mg i.v. (o 500mg in selected cases) in the operating room at the time of revascularization. • MMF 1g PO BID.
POD 1-2	• Methylprednisolone 250 mg i.v. OD. • MMF 1g PO BID. • Tacrolimus 0.1mg/kg PO BID (in rapid steroid descaling protocol).
POD 3 -->	Rapid steroid descaling protocol: • Methylprednisolone 20 mg PO OD. • MMF 1g PO BID. • Tacrolimus 0.1mg/kg PO BID.
	Gradual steroid descaling protocol: • Methylprednisolone 150mg (POD3) --> 100mg (POD4) --> 75mg (POD5) --> 50mg (POD6) --> 20mg (POD7). • MMF 1g PO BID. • Tacrolimus is initiated when the renal function trend is normalizing, with POD7.

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

   2.1. Antithymocyte globulin (ATG) 0,5 mg/Kg i.v OD from POD 0 --> POD 7.

   2.2. Alemtuzumab (Campath) 30 mg slow i.v. infusion.

   2.3. Basiliximab 20 mg i.v OD on POD 0 and POD 4.

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

   2.5. Mycophenolate Mofetil (MYFORTIC) 750 mg PO BID.

2.6. Tacrolimus 0,1 mg / Kg PO BID.

APPENDIX 10: PROTOCOLS FOR ACUTE REJECTION THERAPY

1. Health facility must maintain documentation in the patient's medical record to support that all elements of the protocol were followed.
2. In presence of pathological evidence of acute rejection, lymphocyte infiltrates:
   2.1. Localized in the dermal vessels.
   2.2. In the interface zone between the dermis and epidermis.
   2.3. Around adnexal structures like hair follicles, sweat glands or sebaceous glands.
3. Also could be coupled with other clinical signs of skin rejection, including erythema, maculopapular rash, edema, hair loss, or desquamation of the palm, and nail changes in the fingers.
4. Severe rejection will include necrosis of single keratinocytes and focal separation of the dermis and epidermis.

Acute cell-mediated rejection.	• Methylprednisolone 250 – 500 mg i.v OD x 3 days. • In presence of no responsive rejection or rapidly relapsing rejection: ATG 2-2,5 mg / Kg OD x 7-14 days.
Acute antibody mediated C4d positive rejection (Banff grade I, II).	Methylprednisolone 10 mg / Kg OD x 3 days, thereafter 20 mg OD. • DAY 1: High dose Immunoglobulins (2g/ Kg) or CMV specific Immunoglobulins (100mg / Kg), STAT. • DAY 2: Rituximab 375 mg / m2, STAT.

Severe Acute antibody mediated positive rejection (Banff grade III), thromboitic microangiopathy	Same protocol as for Grade II + Plasmapheresis on DAY 1, 2, 3, 5 and 7. DAY 7, after plasmapheresis: High dose Immunoglobulins (2g/ Kg) or CMV specific Immunoglobulins (100mg / Kg), STAT. DAY 8: Rituximab 375mg / m2, STAT. Monitoring of DSA: on DAY 1 before therapy initiation, DAY 3 after plasmapheresis, DAY 8 after Rituximab administration.

4. Tacrolimus therapy is maintained with target trough levels 10-15 ng/ml, and MMF 1g BID.

5. Antibiotic prophylaxis must be instituted:

   5.1. Ganciclovir at dosage adjusted to renal function, for CMV.

   5.2. Fluconazole 100mg OD x 1 month, Nystatin 1-2 tabs (*500,000 to 1,000,000 units)* PO x 1 month Trimethoprim- Sulfamethoxazole 80 mg OD x 6 months, for Pneumocystis jiroveci.

APPENDIX 11: PROTOCOLS OF CHRONIC ALLOGRAFT DYSFUNCTIONS (CAD) MANAGEMENT

1. Health facility must maintain documentation in the patient's medical record to support that all elements of the protocol were followed.
2. In presence of pathological evidence of chronic rejection:
   - 2.1. Vessel intimal hyperplasia.
   - 2.2. Perivasculitis.
   - 2.3. Obliterative endarteritis of graft vessels.
   - 2.4. Fibrosis and atrophy of graft.

Treatment of non-immunologic factors	• Arterial pressure pharmacological therapy. • Anti-proteinuria therapy (ACE inhibitor). • Dyslipidemia therapy and weight loss in presence of obesity • Glycemic control. • Minimization of Calcineurin Inhibitors (CNI) therapy, if GFR< 40 ml /min.
Treatment of immunologic factors	• Plasmapheresis followed by CMV specific Immunoglobulins (100mg / Kg) on DAY 1, 3, 5, 7. • On DAY 10: DSA dosage --> if still present, repeat the therapy up to a maximum of 3 times / year.

3. CNI therapy conversion to m-TOR inhibitors:

Indications	• Recipient who develops neoplasia. • The occurrence of severe CNI related side effects. • Development of biopsy proven CAD.
Contraindications	• GFR <40 ml/min. • Proteinuria > 800mg/die. • Hyperlipidemia despite adequate therapy with statin.

Scheme	• Progressive imbrication. • "Stop and Go".

4. CMV Infection Therapy

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

5. BKV Infection Therapy

Diagnosis		• Increased creatinine. • Viruria >6 log 10 / ml and viremia >4 log 10 / ml for more than 4 weeks. • Graft biopsy is indicated.
Therapy	STEP 1	Lowering of immunosuppression: • Decrease of antimetabolite dosage (MMF, AZA, m-TOR inhibitor). • Fifty percent (50%) decrease of CNI dosage (target through level <6 for tacrolimus). • Minimization of steroid therapy.
	STEP 2	• Withdrawal of antimetabolites.
	STEP 3	• Leflunomide 100 mg OD x 5 days --> 40 mg OD x 5 days --

		> 20 mg OD as maintenance dosage or switch to Cidofovir.

APPENDIX 12: KEY PERFORMANCE INDICATORS

1. Process.

1.1. Referral To Listing.

Referral to Listing	
Main Domain:	Process.
Subdomain:	Efficiency.
Indicator Definition:	Average number of days from the date the patient was referred to the transplant unit, to the date upon which the patient was listed for transplant.
Calculation:	Numerator: Total count of days from referral to listing. Denominator: The total number of patients listed.
Target:	< 45 days.
Methodology:	Numerator / Denominator.
Measuring Unit:	Number of days between referral and listing.
Reporting Frequency:	Annually.
Desired Direction:	Lower is better.
Rationale:	Metric of access to transplant.
KPI Source:	DHA Standards for Vascularized Composite Allograft (Limb) Transplant Services.

2. Outcomes.

2.1. ICU Length of Stay.

ICU Length of Stay	
Main Domain:	Outcomes.
Subdomain:	Effectiveness and efficiency.
Indicator Definition:	Average number of days in the ICU after transplant surgery.
Calculation:	Numerator: Sum of the number of days in the ICU for all VCA (limb) recipients post-transplant. Denominator: Total number of VCA (limb) transplants.
Target:	< 3 days.
Methodology:	Numerator / Denominator.
Measuring Unit:	Calendar days.
Reporting Frequency:	Monthly.
Desired Direction:	Lower is better.
Rationale:	Metric of outcomes and effectiveness.
KPI Source:	DHA Standards for Vascularized Composite Allograft (Limb) Transplant Services.

2.2. Early Hospital Readmission

Early Hospital Readmission	
Main Domain:	Outcomes.
Subdomain:	Patient safety.
Indicator Definition:	Percentage of patients readmitted to the hospital within 14 days post-transplant.
Calculation:	Numerator: Total number of VCA (limb) transplant patients readmitted to the hospital within 14 days after discharge post-transplant. Denominator: The number of patients who receive a VCA (limb) transplant.
Target:	< 20%.
Methodology:	Numerator / Denominator x 100.
Measuring Unit:	Percentage of early hospital readmissions.
Reporting Frequency:	Quarterly.
Desired Direction:	Lower is better.
Rationale:	Metric of outcomes and patient safety.
KPI Source:	DHA Standards for Vascularized Composite Allograft (Limb) Transplant Services.

2.3. Ninety (90) Day Graft Survival Rate.

Ninety (90) Day Graft Survival Rate	
Main Domain:	Outcomes.
Subdomain:	Effectiveness.
Indicator Definition:	The percentage of transplanted limbs where the graft is still functioning after 90-days post-transplant. A graft is considered failed if there has been graft failure, a retransplant, or death due to failure of the transplanted organ.
Calculation:	Numerator: The total number of limbs that have not encountered graft failure within ninety (90) days post-transplant. Denominator: The total number of transplanted limbs.
Target:	>95%.
Methodology:	Numerator / Denominator x 100.
Measuring Unit:	Percentage of ninety (90) day graft survival.
Reporting Frequency:	Quarterly.
Desired Direction:	Higher is better.
Rationale:	Metric of success with surgical outcomes and effectiveness.
KPI Source:	DHA Standards for Vascularized Composite Allograft (Limb) Transplant Services.

2.4. One-Year Graft Survival Rate.

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