Standards for Vascularized Composite Allograft (Limb) Transplant Services – Random

Name of the Facility: _____

Date of Inspection:_____/_____/_____

Ref.	Description	Yes	No	N/A	Remarks
5.	**Standard One: Registration and Licensure Procedures**				
5.8.	The health facility shall provide documented evidence of the following:				
5.8.1.	Transfer of critical/complicated cases when required.				
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).				
5.11.	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.				
6.	**Standard Two: Health Facility Requirements**	**Final**			
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.				
6.7.	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:				
6.12.	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.				
7.	**STANDARD THREE: HEALTHCARE PROFESSIONALS REQUIREMENTS**				
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.				
7.5.	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.				

7.5.6.	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.				
7.7.	VCA (Limb) Transplant Coordinators shall be assigned in each OTU providing VCA (limb) transplant services, with the following responsibilities:				
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.				
7.8.	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.				
7.9.	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.				
7.11.	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.				
4.2.2.	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.				
8.4.	Always ensure donor and recipient confidentiality.				
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.				
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.				
11.2.	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.				
12.	**STANDARD EIGHT: POST-OPERATIVE CARE**				
12.4.	Long-term post-discharge management of the VCA (limb) transplant recipient is elaborated in Appendix 8.				