Standards for Corneal Transplant Services

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Health Policies and Standards Department

Health Regulation Sector (2024)

ACKNOWLEDGMENT

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

Health Regulation Sector

Dubai Health Authority

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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 practices;
- Managing patient complaints and assuring patient and physician rights are upheld;
- Governing the use of narcotics, controlled and semi-controlled medications;
- Strengthening health tourism and assuring ongoing growth; and
- Assuring management of health informatics, e-health, and promoting innovation.

The Corneal Transplant Services Standard aims to fulfil the following overarching Dubai Health Sector Strategy 2026:

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

EXECUTIVE SUMMARY

A corneal transplantation (also known as keratoplasty) is a surgical procedure that involves replacing a damaged or diseased cornea with healthy donor corneal tissue. The cornea is the clear, dome-shaped surface at the front of the eye that helps focus light. When it becomes damaged due to injury, infection, or diseases like keratoconus, vision can become impaired. During the procedure, the surgeon removes the affected portion of the cornea and replaces it with a clear, healthy donor cornea. The Standards in this document have been developed to ensure that corneal transplant services provided in DHA licensed health facilities are of the highest quality and aligned with current international best practices.

The document elaborates the following:

1. The licensing requirements of a health facility aiming to provide corneal transplant services
2. The health facility requirements
3. The healthcare professional requirements,
4. The consent for corneal transplantation
5. Import corneas requirements
6. Traceability
7. Receipt and storage
8. Handling
9. Biovigilance
10. Corneal transplant indications
11. Post-operative follow-up of corneal transplant recipient

12. Registry and general key performance indicators of corneal transplantation

This standard is aligned with all the applicable UAE laws and legislations related to the subject:

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

DEFINITIONS

Anterior Lamellar Keratoplasty (ALK): surgical procedure that replaces the front layers of the cornea while preserving the deeper layers. It includes both Deep Anterior Lamellar Keratoplasty (DALK) and Superficial Anterior Lamellar Keratoplasty (SALK).

Biovigilance: system for monitoring and reporting serious adverse incidents (events and reactions) associated with tissue transplantation to ensure patient safety.

Cornea: clear dome-shaped surface at the front of the eye that helps focus light.

Cornea graft: part of the human body that has been donated to use in a human recipient.

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

Donation: legal act indicating that a living individual has legally accepted to donate, during his lifetime or after death under a legal will leave for his heirs or permitted successors to donate with no compensation one or more of his/her body organs or part thereof or tissues to another person by way of a transplantation operation.

Endothelial Keratoplasty (EK): type of corneal transplant that involves replacing the innermost layer of the cornea (the endothelium). Subtypes include Descemet's Stripping Endothelial Keratoplasty (DSEK), Descemet's Stripping Automated Endothelial Keratoplasty (DSAEK), which include part of the stromal layer, and Descemet's Membrane Endothelial Keratoplasty (DMEK) that include only Descemet’s membrane and endothelium.

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

Human application: use of tissues or cells on or in a human recipient.

Informed Consent: agreement or permission accompanied by full information on the nature, risks, and alternatives of a surgical or interventional procedure before the physician begins the procedure/treatment. Accordingly, the patient either consents to or refuses treatment.

Patient: person receiving or registered to receive medical treatment. Within the framework of this Standard, the definition is equal to Recipient.

Processing: labour on the corneal grafts, taking place in a tissue bank to evaluate the quality of for tissue and to shape it according to surgical needs for cornea transplantation. The processing includes steps to prevent the potential introduction, transmission, and spread of communicable diseases by allogenic cornea grafts. Processing includes also conservational processes in order to store the tissue over time E.g. by freeze drying, embedding in glycerol for cryopreservation etc.

Penetrating Keratoplasty (PK): full-thickness corneal transplant procedure where all the layers of the damaged cornea are replaced with a healthy donor cornea.

Recall: removal from use of specific, distributed tissues and cells suspected or known to be potentially harmful.

Recipient: patient receiving or registered to undergo transplantation, to receive a tissue graft.

Root cause analysis: structured approach to identify the underlying factors that resulted in the nature, the magnitude, the location and the timing of a harmful or potentially harmful outcome.

Serious Adverse Event (SAE): any untoward occurrence, associated with the chain, from donation to transplantation that might lead to the transmission of communicable disease, to

death or life-threatening, disabling, or incapacitating conditions for patients or which results in, or prolongs, hospitalization or morbidity.

Serious Adverse Reaction (SAR): any unintended response, including communicable disease, in the living donor or in the recipient that might be associated with any stage of the chain from donation to transplantation that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalization or morbidity.

Standard Operating Procedure (SOP): detailed set of instructions that outlines how tissue transplant services are to be performed to maintain safety and quality standards.

Tissue Bank (TB): organization licensed to process, store, and distribute human tissues and cells for clinical use.

Service-Level Agreement (SLA): formal contract between a health facility and a tissue bank, defining the standards, responsibilities, and procedures for the supply and use of tissues.

ABBREVIATIONS

ALK : Anterior Lamellar Keratoplasty

CAP : College of American Pathologists

DALK : Deep Anterior Lamellar Keratoplasty

DHA : Dubai Health Authority

DM : Dubai Municipality

DMEK : Descemet's Membrane Endothelial Keratoplasty

DSAEK: Descemet's Stripping Automated Endothelial Keratoplasty

DSEK : Descemet's Stripping Endothelial Keratoplasty

EBAA : Eye Bank Association of America

EEBA : European Eye Bank Association

EK : Endothelial Keratoplasty

HFG : Health Facility Guidelines

HPSD : Health Policy and Standards Department

HRS : Health Regulation Sector

ICU : Intensive Care Unit

KPIs : Key Performance Indicators

MOHAP: Ministry of Health and Prevention

OCT : Optical Coherence Tomography

OR : Operating Room

PK : Penetrating Keratoplasty

RP : Responsible Person

SAEs : Serious Adverse Event

SALK : Superficial Anterior Lamellar Keratoplasty

SARs : Serious Adverse Reaction

SLA : Service-Level Agreement

SOP : Standard Operating Procedure

TB : Tissue Bank

UAE : United Arab Emirates

1. BACKGROUND

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

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

There are different types of corneal transplants, including:

- Penetrating Keratoplasty (PK): A full-thickness transplant where the entire damaged cornea is replaced.
- Endothelial Keratoplasty (EK): A partial-thickness transplant where only the innermost layers of the cornea are replaced, often used for conditions affecting specifically the innermost corneal layer (endothelium). Depending on what layers are replaced or if the dissection of the tissue is manual or automated, different techniques can have been described; the most known are Descemet's Stripping Endothelial Keratoplasty (DSEK), Descemet's Stripping Automated Endothelial Keratoplasty (DSAEK), and Descemet's Membrane Endothelial Keratoplasty (DMEK).
- Anterior Lamellar Keratoplasty (ALK): Another partial-thickness transplant that replaces only the front layers of the cornea, leaving the deeper layers intact. Deep Anterior Lamellar

Keratoplasty (DALK) and Superficial Anterior Lamellar Keratoplasty (SALK) are subtypes of ALK.

Corneal transplants can restore vision, relieve pain, and improve the appearance of a diseased or injured cornea. The success of the surgery depends on various factors, including the patient's overall eye health, the cause of corneal damage, and adherence to post-operative care. Recovery can take several months, during which the patient needs to follow strict guidelines, including using prescribed eye drops to prevent infection and graft rejection. Despite some risks, corneal transplants are among the most successful organ transplant procedures, offering a new chance for clear vision to those affected by corneal diseases.

This standard is developed to regulate Corneal Transplant Services, with an aim to assure the provision of the highest levels of safety and quality for providing corneal transplant services in DHA licensed health facilities.

2. SCOPE

2.1. Corneal Transplant Services in DHA licensed health facilities.

3. PURPOSE

3.1. To assure the provision of the highest levels of safety and quality Corneal Transplant Services in Dubai Health Authority (DHA) licensed health facilities.

4. APPLICABILITY

4.1. DHA licensed healthcare professionals and health facilities providing Corneal Transplant Services.

5. **STANDARD ONE:** REGISTRATION AND LICENSURE PROCEDURES

5.1. All health facilities providing Corneal Transplant Services shall adhere to the UAE Laws and DHA requirements.

5.2. All Health facilities in Dubai involved in importing, using, or transplanting corneal tissues must adhere to standards in this document.

5.3. Health facilities aiming to provide Corneal Transplant Services shall comply with the DHA licensure and administrative procedures available on the DHA website https://www.dha.gov.ae.

5.4. Licensed health facilities opting to add Corneal Transplant Services shall inform the Health Regulation Sector (HRS) and apply to HRS to obtain permission to provide the required service.

5.5. Health facilities shall have Standard Operating Procedures (SOPs) related to the Corneal Transplant Service. The relevant staff shall be trained to abide by these SOPs.

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

5.6.1. Patient acceptance criteria

5.6.2. Patient assessment and admission

5.6.3. Patient education and Informed consent

5.6.4. Patient health record

5.6.5. Infection control measures and hazardous waste management

5.6.6. Incident reporting

5.6.7. Patient privacy

5.6.8. Medication management

5.6.9. Emergency action plan

5.6.10. Patient discharge/transfer.

5.6.11. Cornea handling and quality control

5.6.12. Surgical protocols

5.6.13. Post-operative care and follow-up

5.6.14. Biovigilance and reporting

5.6.15. Statistics and report procedure(s)

5.7. The health facility shall provide documented evidence of having, or direct access to the following:

5.7.1. Transfer of critical/complicated cases when required

5.7.2. Patient discharge

5.7.3. Clinical laboratory services

5.7.4. Equipment maintenance services

5.7.5. Laundry services

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

5.7.7. Housekeeping services.

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

5.9. 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.

5.10. 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

6.1. Corneal Transplant Services shall only be performed in licensed DHA health facilities.

6.2. The health facility shall meet the health facility requirement as per the DHA Health Facility Guidelines (HFG).

6.3. The health facility shall install facility infrastructure and equipment required for the provision of the Corneal Transplant Services following the manufacturer's specifications, including:

6.3.1. Operating Room (OR): The facility must have a dedicated ophthalmic operating room equipped with specialized instruments and disposable material for corneal surgeries, including an operating microscope, corneal trephines and punches, and optional equipment such as microkeratome for lamellar surgeries

6.3.2. Sterile environment: the operating room must adhere to strict sterile protocols, including air filtration systems to minimize the risk of infection during surgery.

6.3.3. Corneal storage facilities: the facility should have a designed space/room, equipped to store corneal tissue under appropriate conditions (e.g., storing under proper temperature) to maintain its viability until transplantation.

6.3.4. Post-operative care unit: a designated area for immediate post-surgery care and observation is necessary. While an ICU stay is not typically required, facilities must be capable of providing basic recovery monitoring.

6.3.5. Diagnostic equipment: the facility should have diagnostic tools such as slit-lamp biomicroscopes, corneal topography devices, and optical coherence tomography (OCT) to assess corneal health pre- and post-surgery.

6.4. The health facility providing corneal transplant services should have the following services or direct access to such services:

6.4.1. Biochemistry laboratory

6.4.2. Microbiological laboratory/ies to test for the presence of bacteria and viruses on donor remnants after implantation to fulfil the biovigilance requirements.

6.4.3. Pathology laboratory

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

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

6.7. Since corneal transplants are outpatients' surgery, a fully equipped Intensive Care Unit (ICU) are not required. Immediate access to an anaesthesiologist must be guaranteed in case of a life-threatening situation occurs.

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

7.1. Only a DHA licensed health facility can provide Corneal Transplant Services. Its personnel must meet the following personnel requirements to perform Corneal Transplant Services:

7.1.1. Corneal transplant surgery consultant (minimum 1 consultant corneal surgeon): Surgeon who has completed at least 1 year of surgical corneal fellowship training in a recognized international institute or an established senior corneal surgeon with more than 10 years of surgical practice in the field of cornea transplant.

7.1.2. Optometrist: working for the facility with experience in the field of ophthalmology assessment.

7.1.3. Anaesthesiologists: qualified anaesthesiologists to administer anaesthesia and monitor patients during surgery.

7.1.4. Nursing staff: nurses trained in ophthalmic care to assist during surgeries and provide pre- and post-operative care.

7.1.5. Responsible Officer: A member of staff with clinical experience assigned with overseeing tissue management including ordering, receiving, storage, handling, and disposal. This individual is responsible for registering all activities and identification of incoming and transplanted tissues, of the tissue recipients and of the surgeon implanting the tissues. The Responsible Officer generates statistics in order to inform the DHA about the annual level of tissue

transplantation activities, and KPIs and also acts as the point of contact with regulatory bodies, management of recalls where the supplying Tissue Bank (TB) requests the immediate return of distributed tissues for quality or safety reasons.

7.1.6. Laboratory technicians: trained in tissue typing and microbiological testing to ensure cornea safety.

7.2. All personnel involved in processes associated with the management and use of corneas must be adequately trained in technical, ethical, and legal standards. Health professionals must participate in ongoing training and education to stay current with advancements in transplant techniques and patient management depending on their background (i.e. staff must certify attendance to related topic congresses, workshops, courses to be up to date for their role).

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

8. **STANDARD FOUR:** INFORMED CONSENT FOR CORNEAL TRANSPLANTATION

8.1. Informed Consent shall be obtained from all recipients prior to corneal transplant procedure.

8.2. The healthcare professional must provide the recipient with comprehensive information, including:

8.2.1. The objective and foreseeable outcomes of the indicated treatment (corneal transplantation), potential benefits, and the keratoplasty technique approach.

8.2.2. Information on alternative treatments or different keratoplasty techniques if available.

8.2.3. A description of any adverse outcomes reported for the corneal tissue transplant.

8.2.4. An estimate of the frequency of these adverse outcomes.

8.3. The patient should sign a consent form that should include at least the following elements:

8.3.1. Confirmation that the recipient is aware of the use of corneal tissues in the procedure.

8.3.2. Confirmation that the recipient was appropriately informed of any risks to their health associated with the planned application of corneal tissues.

8.3.3. The acceptance by the recipient of the risks described above considering the potential benefits of the treatment.

8.3.4. The possibility of needing anaesthesia for the treatment and the risks associated with the anaesthesia.

8.4. A specific consent form must be signed by the recipient in cases involving novel procedures, such as clinical application procedures.

8.5. If clinical follow-up data collection is proposed, recipients must be informed about the collection and use of their data, in accordance with national legislation.

8.6. The health facilities shall maintain detailed records of the informed consent process, including signed consent forms and documentation of all information provided to the recipient.

8.7. Healthcare professionals involved in the corneal transplant process shall be adequately trained in obtaining informed consent, with a clear understanding of the ethical and legal requirements.

9. **STANDARD FIVE:** IMPORT CORNEAL TISSUE REQUIREMENTS

9.1. Health facilities must comply with national regulations and obtain corneal tissues from a recognized and accredited Tissue Bank (TB) that follows international tissue bank transplantation standards e.g. Eye Bank Association of America (EBAA), European Eye Bank Association (EEBA) or equivalent.

9.2. Health facilities must select a TB that supplies corneal tissues on a non-profit basis from voluntary unpaid donations and ensure that the donor or next of kin gave consent for the donation. Only verified origin tissues of ethically obtained donations should be accepted for transplantation.

9.3. Health facilities must take responsibility for ensuring that the donors of corneas from the TBs have been correctly screened and tested according to international standards, that they are accredited by their national government, and that all quality system

requirements are in place for the procurement, processing, storage and distribution of corneas.

9.4. Written documentation and agreements are key elements in ensuring that verification of equivalent standards of quality and safety takes place. Health facilities must provide information on annual basis to DHA on the imported cornea, its source, and the location where each activity takes place prior to import. Health facilities must have documents which cover the following:

9.4.1. A copy of the primary label, repackage label, external package and transport container.

9.4.2. A list of relevant and up to date versions of SOPs relating to import activities including SOPs on maintaining traceability, reception and storage of imported corneal tissues, management of adverse events and reactions, management of recalls and traceability from donor to recipient.

9.4.3. A detailed description of the criteria used for donor identification, screening and medical evaluation, information provided to the donor or donor family, how consent is obtained from the donor or donor family and whether the donation was voluntary and unpaid or not.

9.4.4. Detailed information on the microbiological tests performed on the donor, the corneal tissues.

9.4.5. Detailed information on the methods used during the processing of the corneal tissues including details of the validation for the critical processing procedure.

9.4.6. A detailed description of the facilities, critical equipment and materials and criteria used for quality control and control of the environment for each activity carried out by the supplying TB.

9.4.7. Detailed information on the conditions (including microbiological testing) for release of corneal tissues by the supplying TB.

9.4.8. A summary of the most recent inspection of the supplying TB by a third country competent authority or authorities including the date of the inspection, type of inspection, the main conclusions, and follow-up of any corrective actions.

9.4.9. A summary of the most recent audit of a third supplying TB carried out by, or on behalf of, the health facility.

9.4.10. Any relevant national or international accreditation.

9.5. A formal Service-Level Agreement (SLA) or contract must be in place between the supplying TB and the health facility to ensure that quality and safety standards, as well as respective responsibilities, are clearly defined and understood. The SLA must:

9.5.1. Be signed, dated, and regularly reviewed (as defined by the parties), but sooner if changes are required.

9.5.2. Comply with relevant laws and regulations set by competent authorities.

9.6. The SLA should include:

9.6.1. Contact details for relevant persons in both parties, including the TB's responsible person.

9.6.2. A clause ensuring that the supplying TB provides the information set out in this document.

9.6.3. Procedures for ordering, including the method of assuring relevant quality and quantity parameters of ordered corneal tissues.

9.6.4. Procedures for the delivery of corneal tissues, including liability for transport.

9.6.5. A statement that storage and preparation of corneal tissues for transplantation at the health facility must comply with all relevant and specific instructions provided by the TB, including adherence to expiry dates.

9.6.6. Procedures at the health facility for the lawful disposal of unused corneal tissues.

9.6.7. Procedures, if permitted, for the return of corneal tissues to the TB, or for use in research.

9.6.8. Responsibility for maintaining traceability and biovigilance, including procedures for timely reporting and investigation of adverse reactions and events, including 'near misses', and procedures for managing corneal tissues recalls and lookbacks.

9.6.9. Procedures, where permitted, for reporting relevant clinical outcome data relating to the quality, safety, and efficacy of the applied corneal tissues by the health facility to the TB.

9.7. Imported corneal tissues must be traceable from donor to recipient and vice versa in accordance with the traceability requirements set out in this document and agreements with the supplying TB must ensure corneal tissues remain traceable.

9.8. Before requesting corneal tissues, the health facility must confirm that the supplying TB is compliant with all relevant legal and technical standards and requirements for the lawful provision of corneal tissues that are safe and of appropriate quality.

10. **STANDARD SIX:** TRACEABILITY

10.1. Health facilities must maintain traceability records from receipt of corneas until 25 years after their clinical use or disposal. The Responsible Officer, as defined in this document, sees to the proper execution of these records. These records must include the following mandatory information:

10.1.1. Identification of the supplying TB

10.1.2. Identification of the clinician/surgeon/health facilities.

10.1.3. Unique product identification.

10.1.4. Identification of the recipient.

10.1.5. Date of application or disposal.

10.2. Details of the cornea transplanted must be recorded in both the recipient's medical record and in the record of the treatment room or operating theatre where the corneas have been transplanted. These records should support rapid tracing of patients or staff who might be at risk due to a particular donation or processing batch.

10.3. Health facilities must maintain an electronic or paper log that records all received, transplanted, and discarded corneas. This log must provide a two-way audit trail to facilitate the rapid identification of corneas in the event of a recall by the TB or DHA, or to identify recipients if a serious adverse reaction or event is reported that may affect one or more recipients or staff treated at the health facility.

10.4. Health facilities must carefully consider the location and method of archiving the traceability log for the required 25-year period. The individual(s) responsible for the maintenance and safe storage of this log must be clearly identified and documented.

10.5. If required by the TB, the health facility must return a traceability form or card with details sufficient to unambiguously identify the recipient and the applied cornea. A copy of this documentation must be retained in the recipient's medical record. Returning the form or card does not release the health facility from its responsibility to maintain traceability records for 25 years after clinical use or disposal.

10.6. The manner of documenting and returning traceability forms or cards must comply with national data-protection regulations. Confidential information must be stored in secure systems, and the recipient's privacy must be always safeguarded.

10.7. Where cornea has been imported into the country, health facilities must ensure that relevant information retained at the overseas supplying TB remains accessible for the required time and ensure that the corneas are traceable from donor to recipient and vice versa.

11. **STANDARD SEVEN:** RECEIPT AND STORAGE

11.1. Once corneal tissues have been distributed by TB for clinical use, their appropriate storage and handling become the responsibility of the health facility. The tissues should be received at a designated reception area. The individual who receives the tissues must handle them based on their specific training and confirm that the tissues have been received with appropriate labelling and associated documentation.

11.2. The label on the primary tissue container (the container in direct contact with the tissues) must provide:

11.2.1. Type of tissues, identification number or code of the tissue, and a lot or batch number where applicable

11.2.2. Identification of the TB

11.2.3. Expiry date

11.2.4. Where corneal tissues are known to be positive for a relevant infectious disease marker, it must be marked as Biological Hazard.

11.3. The following information must be provided either on the label or in accompanying documentation:

11.3.1. Description (definition) and, if relevant, dimensions of the corneal tissue

11.3.2. Morphology and functional data where relevant

11.3.3. Date of distribution of the corneal tissue

11.3.4. Biological determinations carried out on the donor and results

11.3.5. Storage instructions

11.3.6. Instructions for opening the container, package, and any required manipulation/reconstitution

11.3.7. Expiry dates after opening/manipulation

11.3.8. Instructions for reporting serious adverse reactions and/or events

11.3.9. Presence of potential harmful residues or additives or reagents (e.g. antibiotic allergies, ethylene oxide etc.) which may affect the recipient

11.4. The incoming inspection is to be performed when corneal tissues are received and before they are placed into storage or delivered to the operating room. Health facility personnel should verify and properly record that:

11.4.1. Corneal tissue received corresponds to what was ordered and to the information in the accompanying documentation, which must be complete and legible.

11.4.2. Both shipping containers and primary containers are labelled with the information required (see above) and labels are affixed and legible. Separate accompanying documents should provide any information that is not included in the primary container label.

11.4.3. Both the shipping container and the primary container are intact.

11.4.4. Expiry dates of tissues have not been exceeded.

11.4.5. Time spent in transit, including any deviations from the maximum permissible transit time – transit time is the entire time spent in the shipping container including after receipt at the health facility.

11.4.6. Evidence that the required transit conditions were met (such as, if the consignment was on ice, it should be recorded whether any ice remained in the shipping container). The supplying TB should be able to provide, on request, a validation study to show that the method of transport is adequate to maintain the required temperature for a certain period.

11.5. The health facility should establish a procedure for situations where the requirements described above are not met. Deviations should be recorded and followed up. Any serious incidents resulting, for example, in the loss of highly matched tissue or large quantities of unmatched tissue should be reported to the DHA.

11.6. The health facility must follow the storage and handling instructions provided in the package insert that accompanies the corneal tissues, as specified in the contract with the TB.

11.7. Corneal tissues must be stored under specified conditions, which may vary based on the type, method of preservation, and packaging. The health facility must ensure that the storage device (e.g., closet, refrigerator, freezer, liquid nitrogen storage tank, incubator) is:

11.7.1. Regularly maintained and calibrated.

11.7.2. Secure, with restricted access.

11.7.3. Dedicated to the storage of healthcare products and cleaning according to a defined protocol and frequency.

11.7.4. Equipped with functional alarms.

11.7.5. Competent staff that can manage situations of critical dysfunction of equipment, if necessary 24/7.

11.7.6. Supported by emergency backup storage capacity.

11.8. The health facility must continuously monitor storage temperatures and have procedures in place to address any deviations from defined limits. In the event of equipment or power failure, immediate steps must be taken to protect the integrity of the corneal tissues.

11.9. All records related to storage temperatures must be retained for at least 10 years after the clinical use, disposal, or expiry date of the corneal tissues.

11.10. During storage at the health facility, the documentation must be reliably linked and easily accessible.

11.11. Corneal tissues must not be used if they are not accompanied by a package insert specifying the appropriate storage conditions and handling procedures.

11.12. Health facilities must be aware of and comply with these DHA Standards for Corneal Tissue Transplant Services, regarding the storage of tissues or cells, besides of other UAE laws.

12. **STANDARD EIGHT:** HANDLING

12.1. Before opening the primary tissue container, the health facility personnel should repeat the verification of the container, the label and the accompanying documentation.

12.2. There must be confirmation that the conditions of storage since receipt at the health facility have been monitored, adequately maintained and acceptable in line with the instructions provided by TB.

12.3. The label should be checked against the package insert to verify that the material is exactly what was ordered for the patient and matches the label description. The packaging and contents should be inspected for any signs of damage during transport.

12.4. The corneal tissue must be examined once the container is opened to confirm that the anatomical characteristics match the label description.

12.5. Instructions for opening the container or package, and any required manipulation or reconstitution (e.g., thawing, washing, rehydration), must be followed precisely as provided by the TB. This includes adhering to any expiry dates after opening or manipulation and being aware of any potentially harmful residues or reagents that may adversely affect the recipient (e.g., antibiotics, ethylene oxide, DMSO) or the health facility staff.

12.6. Any deviation from the instructions provided by TB is at the discretion of the surgeon, who must take full responsibility for any adverse outcomes resulting from not adhering to the provided instructions.

12.7. Corneal tissues remaining from a clinical procedure must not be used in another patient. Any residue should be discarded as clinical or anatomical waste in accordance with national regulations or returned to the supplying TB for proper disposal.

12.8. Corneal tissues provided to one health facility should not generally be sent to another health facility for clinical application unless the TB manages the process and ensures that the quality and safety requirements are not compromised.

13. STANDARD NINE: BIOVIGILANCE

13.1. Health facilities must have a vigilance and surveillance (V&S) system in place for reporting, investigating, registering, and recording information about serious adverse events (SAEs) and reactions (SARs) which may influence the quality and safety of corneal tissues and which may be associated with any licensable activity, as well as any SAR observed during or after clinical application which may be linked to the quality and safety of corneal tissues.

13.2. The above system must ensure that:

13.2.1. Staff responsibilities for the management of SAEs and SARs are clearly defined.

13.2.2. Immediate actions can be taken to ensure damage limitation, including:

a. Effective use of traceability information to ensure all corneal tissues related to a particular donor or donation can be identified.

b. Recall.

c. notification of other establishments.

d. where necessary, the temporary cessation of licensable activities implicated in the SAE/SAR.

13.3. All healthcare professionals involved in these processes must be trained in biovigilance practices and should actively collaborate to ensure the safety and efficacy of corneal tissue transplantation.

13.4. SARs for corneal transplants include:

13.4.1. primary graft failure (corneal transplant never cleared);

13.4.2. local infection (endophthalmitis or other serious ophthalmic infection);

13.4.3. graft failure due to a defect in the donor tissue, which was out of date, scarred or marked by incisions from previous surgery;

13.4.4. transmission of malignancy (possibly attributable to the transplanted tissue);

13.4.5. transmission of systemic infection (possibly attributable to the transplanted tissue).

13.5. SAEs include:

13.5.1. wrong tissue supplied for the intended surgical procedure;

13.5.2. tissue supplied was damaged or showed signs of unacceptable previous surgery;

13.5.3. tissue supplied beyond its expiry date;

13.5.4. infection detected in organ-culture medium after the cornea was supplied to the surgeon.

13.6. Reporting SARs: SARs may occur during or after procurement in living donors or after the application of tissues in recipients. health facilities are legally obligated to report any known or suspected SARs to the supplying TB and the DHA. Health facilities play

a critical role in identifying relevant factors contributing to SARs and supporting the investigation process.

13.7. Reporting SAEs: SAEs detected by the health facility must be reported immediately to both the TB and the DHA. The TB is responsible for providing health facilities with clear instructions on how to report SARs and SAEs, preferably using standardized documentation. Prompt reporting allows TB to take precautionary measures to prevent harm to other recipients and to initiate a thorough investigation.

13.8. The initial notification to the TB and DHA should be given as soon as possible and within 48 hours of the discovery or determination of the SAE or SAR by the health facility.

13.9. The health facility must collaborate with TB in the investigation of any suspected adverse reactions or events. This collaboration ensures that all relevant information is gathered and that appropriate measures are taken to mitigate risks to current and future recipients.

13.10. TB may recall tissues distributed to a health facility for various reasons, such as new information about a donor's medical history or an error in processing. When a recall is issued, the health facility must rapidly trace all recipients of the implicated tissues. A centralized logbook or electronic database maintaining a two-way audit trail is required for effective recall management. The health facility's Responsible Officer oversees the execution of this administration.

13.11. The health facility must maintain centralized management of all corneal tissues, including detailed records of their receipt, use, or disposal, and identification of recipients. This centralized system is crucial for effective action in cases of disease transmission or other significant safety concerns. The health facility's Responsible Officer oversees the execution of this administration.

13.12. A review may be required as part of an investigation into the safety of corneal tissues previously applied to patients. This review may involve recalling patients for additional testing or other investigations. The maintenance of a two-way audit trail is essential for the effective identification and follow-up of potentially affected patients.

13.13. A follow-up report must be provided to the DHA within 45 days, which outlines the root cause analysis, and the corrective and preventative actions indicated to prevent recurrence.

13.14. Following notification of any SAE or SAR, the DHA may organize an inspection of the licensed tissue bank, or any relevant third-party premises, and can require the tissue bank to carry out such control measures as are deemed appropriate.

13.15. The health facility must ensure that all biovigilance-related documentation is complete, accurate, and securely stored. These records must be retained in accordance with national regulations and should be readily accessible for review by the DHA.

14. **STANDARD TEN:** CORNEAL TRANSPLANT INDICATIONS

14.1. Indications for Penetrating Keratoplasty (PK), including but not limited to:

14.1.1. Primary endothelial failure (mainly Fuchs corneal dystrophy).

14.1.2. Secondary endothelial failure (mainly pseudophakic bullous keratopathy).

14.1.3. Stromal disease (keratoconus, corneal dystrophies with stromal involvement, scars)

14.1.4. Keratitis and similar diseases compromising corneal functions or the integrity of the eye.

14.1.5. Regraft.

14.2. Indications for Endothelial Keratoplasty (EK), including but not limited to:

14.2.1. Primary endothelial failure (mainly Fuchs corneal dystrophy).

14.2.2. Secondary endothelial failure (mainly pseudophakic bullous keratopathy).

14.2.3. Regraft for endothelial decompensation.

14.3. Indications for (Deep) Anterior Lamellar Keratoplasty (ALK/DALK), including but not limited to:

14.3.1. Stromal disease caused by keratoconus, corneal dystrophies, scars and keratitis, or similar diseases compromising corneal function or the integrity of the cornea, when the endothelium of the recipient is assumed to have normal function.

15. **STANDARD ELEVEN:** POST-OPERATIVE FOLLOW-UP OF CORNEAL TRANSPLANT RECIPIENT

15.1. Patients undergoing corneal transplantation require systematic and regular clinical follow-up to meet international standards for patient care. This follow-up can occur solely at the corneal transplant center or be shared between the transplant center and primary or secondary eye clinics, including general ophthalmology practices.

15.2. Regular monitoring is essential to identify complications, such as suture-loosening, endothelial failure, infection (corneal or intraocular), rejection episodes, or increased intraocular pressure.

15.3. The frequency of follow-up visits is tailored to each patient based on the type of corneal transplant, surgical indication, and the presence of potential risk factors. High-risk procedures need closer follow-up.

15.4. Conduct systematic longer-term follow-ups at 2 years post-surgery, as part of an internal quality program. After this period, lifelong annual or biannual visits to an ophthalmologist are recommended for all corneal transplant recipients.

15.5. The systematic follow-ups should register basic clinical and quality criteria, including:

15.5.1. The primary surgical indication, such as improving visual acuity, relieving pain, or preserving eye integrity.

15.5.2. Assessment of graft functionality and clarity.

15.5.3. Measurement of the patient's visual acuity.

15.6. Reporting SARs to the DHA and supplying TB is mandatory.

16. **STANDARD TWELVE:** REGISTRY AND GENERAL KEY PERFORMANCE INDICATORS FOR CORNEAL TRANSPLANT SERVICES

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

16.2. Data from KPIs and registries should be used to identify areas for improvement in the corneal transplant process. Health facilities should implement strategies and interventions to address identified issues and enhance overall outcomes.

16.3. Health facilities should maintain transparency in their KPI reporting and be accountable for the results.

16.4. KPIs should be reviewed and updated regularly to reflect the evolving nature of corneal transplant practices, new technologies, and emerging trends in patient outcomes.

16.5. The accuracy and reliability of the data collected for KPIs should be regularly audited and validated to ensure that the information used for decision-making is trustworthy and actionable.

16.6. Key Performance Indicators

16.6.1. Percentage of trained healthcare professionals involved in Corneal Transplantation on the DHA Standards for Corneal Transplant Services and relevant policies and procedures.

Percentage of Trained Healthcare Professionals Involved in Corneal Transplantation on the DHA Standards for Corneal Tissue Transplant Services and relevant policies and procedures	
Main Domain:	Structure
Subdomain:	Effectiveness
Indicator Definition:	The percentage of healthcare professionals involved in corneal transplantation trained on DHA Standards for Corneal Tissue Transplant Services including all relevant policies and procedures, but not limited to: 1. Registration and licensure procedure; 2. Import corneal tissue requirements; 3. Consent for corneal transplantation; 4. Corneal tissue management including ordering, receiving, storage, handling, and disposal; 5. Traceability; 6. Biovigilance; etc.
Calculation:	Numerator: number of healthcare professionals involved in corneal tissue transplant trained on DHA Standards for Corneal and Tissue Transplant Services. Denominator: total number of healthcare professionals involved in corneal transplantation.
Target:	70%
Methodology:	(Numerator/Denominator) x100

Measuring Unit:	Percentage of trained healthcare professionals involved in corneal transplantation
Reporting Frequency:	Quarterly
Desired Direction:	Higher is better
Rationale:	Training healthcare professionals involved in corneal transplantation on DHA Standards for Corneal Tissue Transplant Services is crucial to ensure that all personnel are knowledgeable and compliant with best practices, enhancing the safety and quality of corneal tissue transplant services, and leading to better transplant outcomes.
KPI Source:	DHA Standards for Corneal Tissue Transplant Services

16.6.2. A formal Service-Level Agreement (SLA) or contract is in place between the supplying Tissue Bank(s) (TB) and the health facility.

A formal Service-Level Agreement (SLA) or contract is in place between the supplying Tissue Bank(s) (TB) and the health facility	
Main Domain:	Structure
Subdomain:	Effectiveness
Indicator Definition:	A formal Service-Level Agreement (SLA) or contract must be in place between the supplying TB and the health facility to ensure that quality and safety standards, as well as respective responsibilities, are clearly defined and understood.
Calculation:	Numerator: Number of supplying TB with a formal SLA or contract Denominator: Total number of supplying TB
Target:	100%
Methodology:	(Numerator / Denominator) x 100
Measuring Unit:	Percentage of supplying TB with a formal SLA or contract
Reporting Frequency:	Quarterly
Desired Direction:	Ever one hundred percentage
Rationale:	SLA or contract between the supplying TB and the health facility is the best way to ensure that quality and safety standards, as well as respective responsibilities, are clearly defined and understood in corneal transplant services.
KPI Source:	DHA Standards for Corneal Tissue Transplant Services

16.6.3. Percentage of informed consent for corneal transplantation obtained from corneal tissue transplant candidates.

Percentage of informed consent for corneal transplant obtained from corneal transplant candidates	
Main Domain:	Process
Subdomain:	Patient Safety
Indicator Definition:	The corneal transplant candidate should sign a consent form before the transplant procedure that should include at least the following elements: a. Confirmation that the recipient is aware of the use of human tissues in the procedure. b. Confirmation that the recipient was appropriately informed of any risks to their health associated with the planned application of human tissues. c. The acceptance by the recipient of the risks described above considering the potential benefits of the treatment. This KPI is defined by the percentage of informed consent for corneal transplantation obtained from corneal transplant candidates.
Calculation:	Numerator: number of informed consents for corneal transplantation obtained from corneal transplant candidates. Denominator: total number of corneal transplantation.
Target:	100%
Methodology:	(Numerator/Denominator) x 100
Measuring Unit:	Percentage of patients
Reporting Frequency:	Quarterly

Desired Direction:	Ever one hundred percentage
Rationale:	Ensuring patient safety through
KPI Source:	DHA Standards for Corneal Tissue Transplant Services

16.6.4. Percentage of serious adverse events (SAEs) and reactions (SARs) after Corneal Transplantation reported to DHA

Percentage of serious adverse events (SAEs) and reactions (SARs) after Corneal Transplantation reported to DHA	
Main Domain:	Process
Subdomain:	Patient Safety
Indicator Definition:	Health facility must have a vigilance and surveillance (V&S) system in place for reporting, investigating, registering, and recording information about serious adverse events (SAEs) and reactions (SARs) which may influence the quality and safety of corneal tissues and which may be associated with any licensable activity, as well as any SAR observed during or after clinical application which may be linked to the quality and safety of tissues and cells. This KPI is defined by the percentage of serious adverse events (SAEs) and reactions (SARs) after a corneal transplant is reported to DHA within 48 hours after it has occurred. A report with the actions taken should be sent quarterly.
Calculation:	Numerator: number of serious adverse events (SAEs) and reactions (SARs) after corneal transplantation is reported to DHA within 48 hours after it has occurred. Denominator: total number of serious adverse events (SAEs) and reactions (SARs) after a corneal transplantation.
Target:	100%
Methodology:	(Numerator / Denominator) x 100
Measuring Unit:	Percentage of SAEs and SARs after a corneal transplantation is

	reported
Reporting Frequency:	Quarterly
Desired Direction:	Ever one hundred percentage
Rationale:	Ensure that all serious adverse events (SAEs) and reactions (SARs) after a corneal transplant are reported for DHA.
KPI Source:	DHA Standards for Corneal Tissue Transplant Services

16.6.5. Percentage of unplanned return to the operating theatre within ≤ 24 hours post-corneal transplant surgery.

Percentage of unplanned return to the operating theatre within ≤ 24 hours post-corneal transplant surgery	
Main Domain:	Outcome
Subdomain:	Effectiveness
Indicator Definition:	The percentage of unplanned returns to the operating theatre within ≤ 24 hours after corneal transplant surgery.
Calculation:	Numerator: **n**umber of unplanned returns to the operating theatre within ≤ 24 hours post-corneal transplant surgery. Denominator: total number of corneal transplant surgeries performed.
Target:	< 5%
Methodology:	(Numerator/Denominator) x 100
Measuring Unit:	Percentage of unplanned returns
Reporting Frequency:	Quarterly
Desired Direction:	Lower is better
Rationale:	To ensure the quality of clinical competence and surgical skills by monitoring and minimizing the rate of unplanned returns to the operating theatre after corneal transplant surgery.
KPI Source:	National Eye Database of Malaysia: https://www.acrm.org.my/ned/kpi.html

16.6.6. Patient Follow-up of at Least 24 Months After Corneal Transplantation

Patient Follow-up of at Least 24 Months After Corneal Transplantation	
Main Domain:	Outcome
Subdomain:	Long-term Patient Care
Indicator Definition:	The percentage of patients who complete a follow-up of at least 24 months after undergoing surgery.
Calculation:	Numerator: number of patients who completed follow-up for at least 24 months. Denominator: total number of patients who underwent surgery at least 24 months ago.
Target:	90%
Methodology:	(Numerator/Denominator) x 100
Measuring Unit:	Percentage of patients
Reporting Frequency:	Quarterly
Desired Direction:	Higher is better
Rationale:	Ensuring long-term patient follow-up improves patient outcomes, monitors the success of the surgery, and allows timely intervention if needed.
KPI Source:	DHA Standards for Corneal Tissue Transplant Services

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