Standards for

Tissue Management

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

The Standards for Tissue Management aim 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

Tissue transplantation is done to replace or repair damaged tissue caused by disease or trauma, restoring normal function in the recipient. The most used tissues for transplantation include ocular (e.g., cornea), cardiovascular (e.g., heart valves), musculoskeletal (e.g., bones, tendons), and skin tissues. While organ donation and transplantation are typically life-saving procedures, tissue transplantation is generally life-enhancing. Unlike organs, tissues can be stored for extended periods, ranging from weeks to several years. This storage capability enables a more thorough risk-benefit assessment before tissue donations are released for clinical use, offering an advantage over the immediate nature of organ transplantation. This document has been developed to ensure the provision of the highest levels of safety and quality in tissue transplantation and the tissues intended for clinical use in DHA licensed health facilities.

The document elaborates on the following:

1. Requirements of a health facility providing tissue transplantation or applying tissue for clinical purposes.
2. The health facility requirements
3. The healthcare professional requirements,
4. The consent for tissue transplantation
5. Import tissue requirements
6. Traceability
7. Receipt and storage
8. Handling

9. Biovigilance

10. Registry and general key performance indicators of tissue transplantation

These Standards for Tissue Management are 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.
- Federal Law no. (8) of 2023 amending some provisions of Federal Law no (4) of 2015 concerning Private Health Facilities.
- Ministerial Decision no. (19) of 2022 concerning the Standards of Death Determination.

ABBREVIATIONS

DHA : Dubai Health Authority

GP : General practitioner

HFG : Health Facility Guideline

HPSD : Health Policy and Standards Department

HRS : Health Regulation Sector

ICU : Intensive Care Unit

KPIs : Key Performance Indicators

SARs : Serious Adverse Reaction

SAEs : Serious Adverse Event

SLA : Service-Level Agreement

SOP : Standard Operating Procedure

TB : Tissue Bank

UAE : United Arab Emirates

V&S : Vigilance and Surveillance

DEFINITIONS

Allogeneic: cells and tissues donated by one person for clinical application to another person.

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

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 left for his heirs or permitted successors, to donate with no compensation one or more of his/her body organs or part thereof or tissues to another person by way of a transplantation operation.

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: refers to the use of tissues or cells on or in a human recipient.

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.

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

Processing: labor on the tissue grafts, taking place in a tissue bank to evaluate the quality of for tissue and to shape it according to surgical needs for tissue transplantation. The Processing includes steps to prevent the potential introduction, transmission, and spread of communicable

diseases by allogenic tissue 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.

Recall: removal from stock to prevent 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.

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

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

Tissue graft: part of the human body that has been donated to use in a human recipient. Within the framework of this standard, the definition is equal to tissue.

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

Traceability: the ability to trace the origin, processing, storage, location, and final use of tissues to ensure compliance with safety standards.

Tissue transplantation: surgical operation in which a tissue graft is implanted to replace or repair damaged tissues, restoring functionality in the recipient.

Vigilance and Surveillance (V&S): system for ongoing monitoring of safety aspects concerning tissue grafts and transplantation thereof to promptly identify, report, and address any serious adverse events or reactions.

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.

Tissue transplantation is performed to replace or repair damaged tissues, restoring functionality in the recipient. Human tissues and cells can be obtained from both living and deceased donors. The use of tissues and cells provides significant therapeutic benefits for a wide range of patients, offering both life-saving interventions (such as skin grafts for burn victims or heart valve transplants) and substantial improvements in quality of life (such as corneal transplants to restore vision or bone grafts for structural support). Living donors undergoing surgical procedures can donate surgical by-products, such as the femoral head during hip replacement or the placenta for amniotic membrane grafts, which are then processed and stored for allogeneic use. The risk associated with the application of human tissues is in principle the same as in organ transplantation. However, by stringent donor screening and processing in a tissue bank, removing blood and other cells, and applying sterilisation steps, the risks are reduced to an absolute minimum.

These standards have been developed to ensure the provision of the highest levels of safety and quality in tissue transplantation and the tissues intended for clinical use in DHA licensed health facilities.

2. SCOPE

2.1. Tissue transplantation and management of tissues for clinical application in DHA licensed health facilities.

3. PURPOSE

3.1. To assure the provision of the highest levels of safety and quality in tissue transplantation and the clinical use of tissues in Dubai Health Authority (DHA) licensed health facilities.

4. APPLICABILITY

4.1. DHA licensed healthcare professionals and health facilities performing tissue transplantation or applying tissue for clinical purposes.

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

5.1. All health facilities performing tissue transplantation or applying tissue for clinical purposes shall adhere to the United Arab Emirates (UAE) Laws and DHA requirements.

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

5.3. Health facility shall have Standard Operating Procedures (SOPs) related to the tissue transplant management. The relevant staff shall be trained to abide by these SOPs.

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

5.4.1. Patient acceptance criteria.

5.4.2. Patient assessment and admission.

5.4.3. Patient education and Informed consent.

5.4.4. Patient health record.

5.4.5. Infection control measures and hazardous waste management.

5.4.6. Incident reporting.

5.4.7. Patient privacy.

5.4.8. Medication management.

5.4.9. Emergency action plan.

5.4.10. Patient discharge/transfer.

5.4.11. Tissue handling and quality control

5.4.12. Surgical protocols

5.4.13. Post-operative care and follow-up

5.4.14. Biovigilance and reporting

5.4.15. Statistics and report procedure(s).

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

5.5.1. Transfer of critical/complicated cases when required.

5.5.2. Patient discharge.

5.5.3. Clinical laboratory services.

5.5.4. Equipment maintenance services.

5.5.5. Laundry services.

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

5.5.7. Housekeeping services.

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

5.7. 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.

5.8. 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. Tissue transplantation shall only be performed in licensed DHA health facilities.

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

6.3. Two main models for the management of tissue distributed to a health facility could be applied:

6.3.1. A decentralized model: a model whereby tissues are delivered directly to the relevant department of the health facility (e.g. orthopaedic, cardio-surgical, ocular) or to the operating theatre. This model offers optimal control by the

tissue users; however, traceability of tissues becomes more difficult and compliance with the requirements for storage and handling is also problematic.

6.3.2. A centralised model: a model where a health facility unit (e.g. Tissue Transplant Unit) takes responsibility for all activities regarding administration of tissues. Centralised models greatly improve the ability to trace tissues and cells and can significantly improve inventory control and compliance with safety and quality. For these reasons, a centralized model for the receipt, short term storage and traceability of tissues and cells for human application is strongly recommended. In a health facility, the blood bank is likely to be the best option for this function. To ensure the traceability, the health facility is required to designate oversight accountability for ordered, received, stored and applied tissues to named individuals and all the activities concerning tissue management should be recorded e.g. in a logbook (see section 'Traceability' below). In the case of a larger health facility, which has its own quality management system, all the above-mentioned activities should be incorporated into this system and the roles and tasks of officially designated personnel should be clearly specified in SOPs.

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

6.5. The health facility performing tissue transplantation or applying tissue for clinical use should have the following services, or direct access to such services:

6.5.1. Biochemistry laboratory

6.5.2. Microbiological laboratory/ies to test for the presence of bacteria and viruses in the remnants of the tissue implanted.

6.5.3. Pathology laboratory

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

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

6.8. The health facility shall have appropriate equipment and trained healthcare professionals to manage critical and emergency cases.

6.9. Health facility opting to perform tissue transplantation that do not have fully equipped Intensive Care Unit (ICU) capabilities, immediate access to an anaesthesiologist must be guaranteed in case of a life-threatening situation occurs.

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

7.1. Healthcare professionals involved in tissue transplantation shall meet the following personnel requirements:

7.1.1. Surgeon: must have certification and specialized training relevant to the type of tissue transplantation (e.g., ophthalmologists for corneal transplants, orthopaedic surgeons for bone grafts, etc.). The surgeon has the ultimate responsibility to check the documentation attached and to evaluate the tissue before implantation to ensure accuracy and quality.

7.1.2. Physicians: must be qualified to perform pre-operative assessments and post-operative care, including monitoring for transplant-related risks and complications.

7.1.3. Nursing staff: must receive specialized training in transplant procedures, including pre- and post-operative care.

7.1.4. Responsible Officer: a member of staff with clinical experience assigned to 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, and management of recalls where the supplying tissue bank (TB) requests the immediate return of distributed tissues for quality or safety reasons.

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

7.2. All personnel involved in processes associated with the management and use of tissues and cells 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.

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 at 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 TISSUE TRANSPLANTATION

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

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

8.2.1. A description of any adverse outcomes reported for the specific type of tissue or cell application.

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

8.2.3. Whether the treatment involves novel methods of processing or clinical application.

8.2.4. Information on alternative treatments, if available.

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 human 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 human 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 for the need of 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 facility 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 tissue transplant process shall be adequately trained in obtaining informed consent, with a clear understanding of the ethical and legal requirements.

9. **STANDARD FIVE:** IMPORT TISSUES 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 tissues and cells 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 tissues or cells 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 tissues or cells.

9.4. Written documentation and agreements are key elements in ensuring that verification of equivalent standard of quality and safety takes place. Health facilities must provide information on annual basis to DHA on each imported tissue, cell, and product type, its source, and the location where each activity takes place prior to import. Health facilities must have documents that 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 tissues and cells, 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 and screening, 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 donor, the tissues and cells.

9.4.5. Detailed information on the methods used during the processing of the tissues and cells 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 for release of tissues and cells by the supplying TB.

9.4.8. A summary of the most recent inspection of the supplying TB by the 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 the 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 (RP).

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

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

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

9.6.5. A statement that storage and preparation of tissues and cells for human application 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 tissues or cells or remnants of tissues and cells after human application.

9.6.7. Procedures, if permitted, for the return of tissues or cells 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 tissue and cell 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 tissues or cells by the health facility to the TB.

9.6.10. The option for TB and health facility to conduct an audit of the other party.

9.7. Imported tissues and cells 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 tissues and cells remain traceable.

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

10. **STANDARD SIX:** TRACEABILITY

10.1. Health facilities must maintain traceability records from receipt of tissues or cells 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 facility.

10.1.3. Type of tissues or cells.

10.1.4. Unique product identification.

10.1.5. Identification of the recipient.

10.1.6. Date of application or disposal.

10.2. Details of the tissues or cells applied must be recorded in both the recipient's medical record and in the record of the treatment room or operating theatre where the tissues or cells have been applied. 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 tissues or cells. This log must provide a two-way audit trail to facilitate the rapid identification of tissues and cells 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 tissues or cells. 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 material has been imported into the country, health facility must ensure that relevant information retained at the overseas supplying TB remains accessible for the required time and ensure that the tissues and cells are traceable from donor to recipient and vice versa.

10.8. When patients treated with human tissues or cells are discharged, their discharge documents should note this. The patient's general practitioner should be informed so they can watch for any unexpected symptoms related to the tissues or cells. The GP should also be advised to report unusual findings back to the health facility.

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

11.1. Once tissues or cells have been distributed by a 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. In the case of autologous donation, this must be specified (for autologous use only) and the donor/recipient must be identified.

11.2.5. Where 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 tissue

11.3.2. Morphology and functional data where relevant

11.3.3. Date of distribution of the 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 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. The 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 tissues or cells, as specified in the contract with the TB.

11.7. Tissues and cells 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 tissues or cells.

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 tissues or cells.

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

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

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 the 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 tissue graft must be examined once the container is opened to confirm that the anatomical characteristics (e.g., left versus right femur, aortic versus pulmonary heart valve) match the label description. Tissues intended for surgical use should be clearly specified and documented in the surgical checklist.

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 the 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. Tissues or cells 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. A single unit of tissues or cells must not be used for more than one patient.

12.8. Certain types of tissues (e.g., bone grafts) that are received but not used in one recipient or department of a health facility may occasionally be reallocated to a different recipient or department within the same health facility. If this occurs, safety, quality, and traceability measures must be in place with clear documentation. This activity must be specified in the overall quality-system documentation and in the SLA with the supplying TB.

12.9. Tissues or cells 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 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 tissues and cells 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.

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 tissues and cells 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 tissue and cell transplantation.

13.4. Reporting SARs: SARs may occur during or after procurement in living donors or after the application of tissues or cells 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.

13.5. 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 the TB to take precautionary measures to prevent harm to other recipients and to initiate a thorough investigation.

13.6. 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.

13.7. 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.

13.8. A TB may recall tissues or cells 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 or cells. 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.

13.9. Health facility must maintain centralized management of all tissues and cells, 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.

13.10. A review may be required as part of an investigation into the safety of tissues or cells 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.

13.11. 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.

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

13.13. Health facilities 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: REGISTRY AND GENERAL KEY PERFORMANCE INDICATORS FOR TISSUE MANAGEMENT

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

14.2. Data from KPIs and registries should be used to identify areas for improvement in the tissue management. Health facilities should implement strategies and interventions to address identified issues and enhance overall outcomes.

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

14.4. KPIs should be reviewed and updated regularly to reflect the evolving nature of tissue management, new technologies, and emerging trends in patient outcomes.

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

14.6. Key Performance Indicators

14.6.1. Percentage of trained healthcare professionals involved in tissue management on the DHA Standards for Tissue Management and relevant policies and procedures.

Percentage of Trained Healthcare Professionals Involved in Tissue Management on the DHA Standards for Tissue Management and relevant policies and procedures	
Main Domain:	Structure
Subdomain:	Effectiveness

Indicator Definition:	The percentage of healthcare professionals involved in tissue management trained on DHA Standards for Tissue Management including all relevant policies and procedures, but not limited to: 1. Registration and licensure procedure. 2. Import tissue requirements. 3. Consent for tissue transplantation. 4. Tissue management, disposal, ordering, receiving, storage, handling, and disposal. 5. Traceability. 6. Biovigilance.
Calculation:	Numerator: number of healthcare professionals involved in tissue management trained on DHA Standards for Tissue Management Denominator: total number of healthcare professionals involved in tissue management.
Target:	70%
Methodology:	(Numerator/ denominator) x100
Measuring Unit:	Percentage of trained healthcare professionals involved in tissue management
Reporting Frequency:	Quarterly
Desired Direction:	Higher is better
Rationale:	Training healthcare professionals involved in tissue management on DHA Standards for Tissue Management is crucial to ensure that all personnel are knowledgeable and compliant with best practices, enhancing the safety and quality of tissue management, and leading to better transplant outcome.
KPI Source:	DHA Standards for Tissue Management

14.6.2. 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. The SLA or contract requirements are well described in Standard Five: Import Tissues Requirements these DHA Standards.
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 tissue management.
KPI Source:	DHA Standards for Tissue Management

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

Percentage of informed consent for tissue transplantation obtained from tissue transplant candidates	
Main Domain:	Process
Subdomain:	Patient Safety
Indicator Definition:	The tissue 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 tissue transplantation obtained from tissue transplant candidates.
Calculation:	Numerator: number of informed consents for tissue transplantation obtained from tissue transplant candidates. Denominator: total number of tissue 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 Tissue Management

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

Percentage of serious adverse events (SAEs) and reactions (SARs) after Tissue 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 tissues and cells 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 tissue transplantation 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 a tissue 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 tissue transplantation.
Target:	100%
Methodology:	(Numerator/Denominator) x 100

Measuring Unit:	Percentage of SAEs and SARs after a tissue 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 tissue transplant are reported for DHA.
KPI Source:	DHA Standards for Tissue Management

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