Guidelines for Reporting Human Organ and Tissue Donation Services Registry and Key Performance Indicators

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Health Policies and Standards Department

Health Regulation Sector (2022)

INTRODUCTION

Health Regulation Sector (HRS) forms an integral part of Dubai Health Authority (DHA) and is mandated by DHA law No. (14) of the year (2021) amending some clauses of law No. (6) of 2018 pertaining to the Dubai Health Authority (DHA), to undertake several functions including but not limited to:

- Developing regulation, policy, standards, 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.
- Managing health advertisement and marketing of healthcare products.
- Governing the use of narcotics, controlled, and semi-controlled medications.
- Strengthening health tourism and assuring ongoing growth.
- Assuring management of health informatics, e-health, and promoting innovation.

The Guidelines for Reporting Human Organ & Tissue Donation Services Registry and Key Performance Indicators aims to fulfil the following overarching DHA Strategic Priorities (2022-2026):

- Make Dubai a lighthouse for healthcare governance, integration and regulation.
- Foster healthcare education, research and innovation.
- Strengthening the economic contribution of the health sector, including health tourism to support Dubai economy.

ACKNOWLEDGMENT

The Health Policies and Standards Department (HPSD) developed this Guideline in collaboration with Subject Matter Experts nationally and internationally, the National Organ and Tissue Donation and Transplant Committee, and the Supervisory Committee for Human Organs and Tissues Transplantation Program in the Emirate of Dubai and would like to acknowledge and thank these health professionals for their dedication toward improving quality and safety of healthcare services in the Emirate of Dubai.

Health Regulation Sector

Dubai Health Authority

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EXECUTIVE SUMMARY

Human organ and tissue donation services are considered critical support areas to the healthcare system. Several laws exist in the United Arab Emirates to guide and support death determination and deceased organ donation including:

- Federal Law no. (4) of 2016 on Medical Liability;
- Federal Decree no. (5) of 2016 on Regulating the Transfusion and Transplantation of Human Organs and Tissues;
- Cabinet Decision no. (25) of 2020 concerning Federal Decree no. (5) of 2016 on Regulating the Transfusion and Transplantation of Human Organs and Tissues;
- Cabinet Decision no. (40) of 2019 concerning the Federal Decree of Medical Liability Law; and
- Ministerial Decision no. (19) of 2022 concerning the Requirements for Determining Death.

Dubai Health Authority has issued the Standards for Human Organs & Tissues Donation Services (Deceased Donor) that sets out the requirements for determining death by neurological criteria in hospitals with active intensive care units and require hospitals to report a registry and set of key performance indicators. Key Performance Indicators are a set of defined and measurable values that are used to determine progress towards a specific goal. They are used to provide evidence and inform decision making on the areas they measure.

This document provides a guidance to hospitals on reporting a set of four (4) Key Performance Indicators (KPIs) and the organ donation registry. A description of each KPI is provided in a KPI card to ensure proper reporting. Providers are expected to share the registry

and KPIs on a monthly basis using the provided Registry template. The KPIs covered in the guidelines are as follows:

- Percentage of trained ICU staff on the DHA Standards for Human Organs & Tissues Donation Services, and relevant Policies and Procedures.
- Percentage of Notification of All Possible Death by Neurological Criteria (DNC) Donors in the ICU.
- Percentage of Death Declaration by Neurological Criteria.
- Percentage of Referral of Potential Death by Neurological Criteria (DNC) Donor.

Statistics and data on:

- Percentage of Unified Consent Form.
- ICU Mortality Rate.
- Data requested for Registry of Organ Donation and Tissue Transplantation.

DEFINITIONS

Death by Neurological Criteria (DNC): Is defined as the irreversible cessation of all functions of the entire brain, including the brainstem, loss of the capacity for consciousness combined with the irreversible loss of all brain and brainstem functions, including the capacity to spontaneous breathing. Brain Death determined by neurological criteria is equivalent to the death of the individual, even though the heart continues to beat and spinal cord functions may persist in accordance with the criteria set out in the Ministerial Decision No. (19) Of 2022, Concerning the Criteria for the Diagnosis of Death.

Comatose Patients: Patients with Glasgow Coma Scale (GCS< 8) on admission to the hospital or during ICU management reasonably not caused by sedation.

Cerebral Lesion: is any cerebral lesion potentially causing (or being co-factor of or complication) death by neurological criteria in ICU. This also includes:

- Acute cerebral lesion (brain trauma, postanoxic, stroke etc.) that supervenes as a complication.
- Subacute or chronic disorders such as brain tumours when acute transformation occurs like spontaneous or postoperative intracranial hypertension, haemorrhagic and cerebral oedema occur.

Organ Donation Unit (ODU): a 24/7 operating unit within the health facility's ICU responsible for all organ donation matters, ran by a director of the unit and a unit coordinator(s).

Organ Donation Unit Director: an ICU intensivist that leads the ODU including all standard operation procedures required for the unit, supervise organ donation unit team and coordinators and oversees implementation of all steps of organ donation process.

Organ Donation Unit Coordinator (ODUC): an ICU nurse, Intensivist or other trained clinical staff assigned by the health facility management, responsible for ensuring all communications between the ODU, DHA and the Emirate Organ and Tissue Center (EOTC) are done on timely manner to facilitate organ donation and transplant.

Patient Identification: Patient with cerebral lesion admitted to the ICU who are identified and reviewed by the Organ Donation Unit Coordinator within 24 hours of meeting the clinical criteria. Identified patients are documented in an organ donation registry (in which clinical data and the time of triggering are reported) that is maintained by the Organ Donation Unit Coordinator.

Possible Death by Neurological Criteria (DNC) Donor: an individual of any age with Glasgow Coma Scale of <8, on mechanical ventilation and experienced a cerebral lesion with severe neurological insult (post resuscitation, cerebral anoxia, Cerebrovascular Accident (CVA), cerebral haemorrhage, encephalopathy, traumatic brain injury).

Potential Death by Neurological Criteria (DNC) Donor: an individual of any age with Glasgow Coma Scale of <5, on mechanical ventilation and experienced a cerebral lesion with severe neurological insult (post resuscitation, cerebral anoxia, CVA, cerebral haemorrhage, encephalopathy, traumatic brain injury).

ABBREVIATIONS

DHA : Dubai Health Authority

DNC : Death by Neurological Criteria

EOTC : Emirates Organ and Tissue Center

GCS : Glasgow Coma Scale

HRS : Health Regulation Sector

ICU : Intensive Care Unit

KPI : Key Performance Indicator

ODU : Organ Donation Unit

ODUC : Organ Donation Unit Coordinator

1. BACKGROUND

As the United Arab Emirates' healthcare system continues to improve and the standards for the quality of care is elevated, critical areas such as death determination by neurological criteria and promotion of deceased organ donation remain significant in further improving the health system functioning and saving lives of those suffering from chronic conditions. Several laws exist in the United Arab Emirates to guide and support death determination and deceased organ donation including:

- Federal Law no. (4) of 2016 on Medical Liability;
- Federal Decree no. (5) of 2016 on Regulating the Transfusion and Transplantation of Human Organs and Tissues;
- Cabinet Decision no. (25) of 2020 concerning Federal Decree no. (5) of 2016 on Regulating the Transfusion and Transplantation of Human Organs and Tissues;
- Cabinet Decision no. (40) of 2019 concerning the Federal Decree of Medical Liability Law; and
- Ministerial Decision no. (19) of 2022 concerning the Requirements for Determining Death.

Dubai Health Authority has issued the Standards for Human Organs & Tissues Donation Services (Deceased Donor) that aligns the diagnosis of death by neurological criteria with international and national best practice and support the organ donation and transplantation efforts at the Emirate and national level. This Guidelines aim to assist hospitals in understanding DHA's Human Organ and Tissue Donation Services Registry and KPIs and their reporting method.

2. PURPOSE

2.1. To ensure reliable and valid reporting of Human Organ and Tissue Donation Services indicators.

2.2. To support federal and Emirate level efforts in the promotion of organ donation.

3. SCOPE

3.1. Measurement and reporting of KPIs by DHA licensed hospitals.

4. APPLICABILITY

4.1. All DHA licensed Hospitals with functioning Intensive Care Units (ICU).

5. GENERAL PROCEDURES

5.1. All DHA licensed hospitals with active intensive care units are required to report the indicators.

5.2. Each hospital is encouraged to assign an organ donation unit coordinator (ODUC) who will be responsible for reporting the indicators.

5.3. Each hospital is required to establish and maintain an organ donation registry and share it with the DHA on a monthly basis using the template circulated by DHA.

5.4. If the KPI is not applicable to the hospital, ODUC should mark the field with “NA”.

5.5. Medical Directors of hospitals and Organ Donation Unit Directors should ensure staff awareness of the KPIs and organ donation registry.

5.6. Hospitals should consider the following in data collection:

5.6.1. Ensure ODUC are adequately skilled and resourced.

5.6.2. Create a data collection plan based on rigor methodology and available resources.

5.6.3. Ensure adequate data collection systems and tools are in place.

5.6.4. Back up the data and ensure protection of data integrity.

5.7. Data Analysis and Submission:

5.7.1. Hospitals must ensure data is clean and analysed for reliability and accuracy before submission.

5.7.2. Data submission should be on a monthly basis.

5.7.3. Submission deadline is the first week of each month.

5.7.4. Submissions should be using the DHA Organ Donation and Tissue Transplantation Registry Template.

5.7.5. Each report will build on the previous one within a calendar year (i.e. February report will present January and February data each in their respective rows).

5.7.6. Data submission can be communicated to the Monitoring and Evaluation Section at the Health Regulation Sector (MonitoringKPIs@dha.gov.ae).

5.8. Hospital Medical Directors and Organ Donation Unit Director are encouraged to review findings with the respective teams to promote performance improvement.

6. KEY PERFORMANCE INDICATORS

6.1. Structure

6.1.1. Percentage of Trained ICU staff on the DHA Standards for Human Organs & Tissues Donation Services, and relevant Policies and Procedures

Percentage of Trained ICU staff on the DHA Standards for Human Organs & Tissues Donation Services, and relevant Policies and Procedures	
Main Domain:	Structure.
Subdomain:	Effectiveness.
Indicator Definition:	Availability of internal policies and procedures that cover all relevant donation steps and as per DHA Standards which include but not limited to: 1. Donor identification and referral; 2. Death declaration; 3. Donor evaluation; 4. Donor maintenance; 5. Family approach; 6. Operating theatre organisation; 7. Communication between ICU professionals, ODU and EOTC; and 8. Organ packaging and transportation (if applicable). Training ICU staff on the Standards for Human Organs & Tissues Donation Services, policies and procedures promote better practice.
Calculation:	Numerator: Number of ICU staff trained on DHA Standards for Human Organs & Tissues Donation Services, and relevant internal policies and procedures. Denominator: Total number of ICU professionals.
Target:	70%.
Methodology:	Numerator/ denominator x100
Measuring Unit:	Percentage of trained ICU staff.
Reporting Frequency:	Monthly.
Desired Direction:	Higher is better.
Rationale:	Metric of structure effectiveness.
KPI Source:	DHA Standards for Human Organs & Tissues Donation Services.

6.2. **Process**

6.2.1. Percentage of Identification of All Possible Death by Neurological Criteria (DNC) Donors in the ICU

Percentage of Notification of All Possible Death by Neurological Criteria (DNC) Donors in the ICU	
Main Domain:	Process.
Subdomain:	Efficiency and effectiveness.
Indicator Definition:	Percentage of patients with cerebral lesion admitted to the ICU who are identified and reviewed by the Organ Donation Unit Coordinator within 24 hours of meeting the clinical criteria and a notification is sent to: • Organ Donation Unit at the Health facility, and • DHA Organ Donation Coordinator* Clinical Criteria for Identification of Critical Care Cases who are Possible Organ Donor: • GCS < 8 and on mechanical ventilation and experienced cerebral lesion (as per the definitions and ICD 10 codes, Appendix 1).
Calculation:	Numerator: Number of comatose patients with cerebral lesion admitted to the ICU who are identified and reviewed by the Organ Donation Unit Coordinator within 24 hours of meeting the clinical criteria. Denominator: Total number of comatose patients with cerebral lesion admitted to the ICU meeting the criteria for identification of critical care cases.
Target:	75%.
Methodology:	Numerator/ denominator x100.
Measuring Unit:	Percentage of identified possible donors.
Reporting Frequency:	Monthly.
Desired Direction:	Higher is better.
Rationale:	Metric of process efficiency.
KPI Source:	Ministerial Decision (19) of 2022, DHA Standards for Human Organs & Tissues Donation Services.

*Refer to DHA Standards for Human Organ and Tissue Donation Services for relevant forms and contact information for coordinators

6.2.2. Percentage of Death Declaration by Neurological Criteria

Percentage of Death Declaration by Neurological Criteria	
Main Domain:	Process.
Subdomain:	Effectiveness and continuity of care.
Indicator Definition:	Percentage of patients with cerebral injury or lesion declared dead by neurological criteria (DNC) through filling the Death by Neurological Criteria Documentation Form.
Calculation:	Numerator: Number of patients with cerebral injury or lesion declared dead by neurological criteria. Denominator: Total number of deaths of patients with cerebral injury or lesion.
Target:	75%.
Methodology:	Numerator/ denominator x100.
Measuring Unit:	Percentage DNC deaths.
Reporting Frequency:	Monthly.
Desired Direction:	-
Rationale:	Metric of effectiveness.
KPI Source:	Ministerial Decision (19) of 2022, ODEQUS, DHA Standards for Human Organs & Tissues Donation Services.

*ICD Codes for acute cerebral lesions can be found in Appendix 1.

6.2.3. Percentage of Referral of Potential Death by Neurological Criteria (DNC) Donor

Percentage of Referral of Potential Death by Neurological Criteria Donor	
Main Domain:	Process.
Subdomain:	Effectiveness.
Indicator Definition:	Percentage of potential Death by Neurological Criteria (DNC) Donors who are referred to: • Organ Donation Unit at health facilities in Dubai; • DHA Organ Donation Coordinator; and • Emirates Organ and Tissue Center (EOTC) team* As per the criteria as soon as possible, and not exceeding 12 hours. Clinical Criteria for Referral of Critical Care Cases who are Potential DDNC donor: • GCS < 5 and intubated and cerebral lesion (ICD 10 codes, Appendix 1).
Calculation:	Numerator: Number of potential DNC donors referred to EOTC within 12 hours. Denominator: Total number of potential DNC donors meeting the criteria for referral.
Target:	100%
Methodology:	Numerator/ denominator x100.
Measuring Unit:	Percentage of referred potential DNC donors.
Reporting Frequency:	Monthly.
Desired Direction:	Higher is better.
Rationale:	Metric of process effectiveness.
Source:	Ministerial Decision (19) of 2022, ODEQUS, DHA Standards for Human Organs & Tissues Donation Services.

*Refer to DHA Standards for Human Organ and Tissue Donation Services for relevant forms and contact information for coordinators

6.3. **Statistical Data**

6.3.1. Percentage of unified consent form

- Is the percentage of potential donors for whom any next of kin or legal guardian has been interviewed by the Emirates Organ and Tissue Center (EOTC) in the presence of the most responsible physician (MRP) or deputy, and have no opposition after interview within the reported period using the unified consent form*.
- Formula: (Number of no oppositions/ total number of interviewed families**)x100.

6.3.2. ICU Mortality Rate

- Is the proportion of patients who die during or shortly after admission to hospital Intensive Care Unit (ICU) in the reported period.
- Formula: number of patients who die in the hospital ICU during or after admission/ total number of ICU admitted patients.

6.3.3 Data requested for the Registry of organ donation and tissue transplantation which include:

- Patient identification data.
- Causes and date of Admission of Ventilated / Comatose Patients.
- Date of Transfer/ Discharge from ICU / Organ Recovery.
- Length of admission in ICU (number of days).
- Discharge Outcome.
- Presence of Medical Contraindication.
- Family Consent Outcome.
- Transplants Performed.
- Post Mortem Care.
- Other as requested.

REFERENCES

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APPENDICES

APPENDIX 1: ICD-10 Codes for Deaths with Acute Cerebral Lesion

Condition	ICD Code(s)	Description
Trauma	S06.1X7A	Traumatic cerebral edema with loss of consciousness of any duration with death due to brain injury prior to regaining consciousness, initial encounter
	S06.1X8A	Traumatic cerebral edema with loss of consciousness of any duration with death due to other cause prior to regaining consciousness, initial encounter
	S06.2X7A	Diffuse traumatic brain injury with loss of consciousness of any duration with death due to brain injury prior to regaining consciousness, initial encounter
	S06.2X8A	Diffuse traumatic brain injury with loss of consciousness of any duration with death due to other cause prior to regaining consciousness, initial encounter
	S06.307A	Unspecified focal traumatic brain injury with loss of consciousness of any duration with death due to brain injury prior to regaining consciousness, initial encounter
	S06.308A	Unspecified focal traumatic brain injury with loss of consciousness of any duration with death due to other cause prior to regaining consciousness, initial encounter
	S06.317A	Contusion and laceration of right cerebrum with loss of consciousness of any duration with death due to brain injury prior to regaining consciousness, initial encounter
	S06.318A	Contusion and laceration of right cerebrum with loss of consciousness of any duration with death due to other cause prior to regaining consciousness, initial encounter
	S06.327A	Contusion and laceration of left cerebrum with loss of consciousness of any duration with death due to brain injury prior to regaining consciousness, initial encounter
	S06.328A	Contusion and laceration of left cerebrum with loss of consciousness of any duration with death due to other cause prior to regaining consciousness, initial encounter

	S06.337A	Contusion and laceration of cerebrum, unspecified, with loss of consciousness of any duration with death due to brain injury prior to regaining consciousness, initial encounter
	S06.338A	Contusion and laceration of cerebrum, unspecified, with loss of consciousness of any duration with death due to other cause prior to regaining consciousness, initial encounter
	S06.347A	Traumatic hemorrhage of right cerebrum with loss of consciousness of any duration with death due to brain injury prior to regaining consciousness, initial encounter
	S06.348A	Traumatic hemorrhage of right cerebrum with loss of consciousness of any duration with death due to other cause prior to regaining consciousness, initial encounter
	S06.357A	Traumatic hemorrhage of left cerebrum with loss of consciousness of any duration with death due to brain injury prior to regaining consciousness, initial encounter
	S06.358A	Traumatic hemorrhage of left cerebrum with loss of consciousness of any duration with death due to other cause prior to regaining consciousness, initial encounter
	S06.367A	Traumatic hemorrhage of cerebrum, unspecified, with loss of consciousness of any duration with death due to brain injury prior to regaining consciousness, initial encounter
	S06.368A	Traumatic hemorrhage of cerebrum, unspecified, with loss of consciousness of any duration with death due to other cause prior to regaining consciousness, initial encounter
	S06377A	Contusion, laceration, and hemorrhage of cerebellum with loss of consciousness of any duration with death due to brain injury prior to regaining consciousness, initial encounter
	S06.378A	Contusion, laceration, and hemorrhage of cerebellum with loss of consciousness of any duration with death due to other cause prior to regaining consciousness, initial encounter
	S06.387A	Contusion, laceration, and hemorrhage of brainstem with loss of consciousness of any duration with death due to brain injury prior to regaining consciousness, initial encounter

	S06.388A	Contusion, laceration, and hemorrhage of brainstem with loss of consciousness of any duration with death due to other cause prior to regaining consciousness, initial encounter
	S06.4X7A	Epidural hemorrhage with loss of consciousness of any duration with death due to brain injury prior to regaining consciousness, initial encounter
	S06.4X8A	Epidural hemorrhage with loss of consciousness of any duration with death due to other causes prior to regaining consciousness, initial encounter
	S06.5X7A	Traumatic subdural hemorrhage with loss of consciousness of any duration with death due to brain injury before regaining consciousness, initial encounter
	S06.5X8A	Traumatic subdural hemorrhage with loss of consciousness of any duration with death due to other cause before regaining consciousness, initial encounter
	S06.6X7A	Traumatic subarachnoid hemorrhage with loss of consciousness of any duration with death due to brain injury prior to regaining consciousness, initial encounter
	S06.6X8A	Traumatic subarachnoid hemorrhage with loss of consciousness of any duration with death due to other cause prior to regaining consciousness, initial encounter
	S06.817A	Injury of right internal carotid artery, intracranial portion, not elsewhere classified with loss of consciousness of any duration with death due to brain injury prior to regaining consciousness, initial encounter
	S06.818A	Injury of right internal carotid artery, intracranial portion, not elsewhere classified with loss of consciousness of any duration with death due to other cause prior to regaining consciousness, initial encounter
	S06.827A	Injury of left internal carotid artery, intracranial portion, not elsewhere classified with loss of consciousness of any duration with death due to brain injury prior to regaining consciousness, initial encounter
	S06.828A	Injury of left internal carotid artery, intracranial portion, not elsewhere classified with loss of consciousness of any duration

		with death due to other cause prior to regaining consciousness, initial encounter
	S06.897A	Other specified intracranial injury with loss of consciousness of any duration with death due to brain injury prior to regaining consciousness, initial encounter
	S06.898A	Other specified intracranial injury with loss of consciousness of any duration with death due to other cause prior to regaining consciousness, initial encounter
	S06.9X7A	Unspecified intracranial injury with loss of consciousness of any duration with death due to brain injury prior to regaining consciousness, initial encounter
	S06.9X8A	Unspecified intracranial injury with loss of consciousness of any duration with death due to other cause prior to regaining consciousness, initial encounter
Cerebrovascular Accidents	I60#	Subarachnoid Hemorrhage
	I61#	Intracranial Hemorrhage
	I62#	Other Non-Traumatic Intracranial Hemorrhage
	I63#	Cerebral Infarction
	I65#	Occlusion And Stenosis Of Precerebral Arteries
	I66#	Occlusion And Stenosis Of Cerebral Arteries
	I67.9	Unspecified Cerebrovascular Accident
Cerebral Damage	G93.1	Anoxic Brain Damage
	G93.5	Compression Of Brain
	G93.6	Cerebral Oedema
Cerebral Neoplasm	C71#	Malignant Neoplasm Of The Brain
	D33#	Benign Neoplasm of the Brain
Infections	G00-G0#	Meningitis
Brain Death	G93.82	Brain Death