

# A Concept Note on System Improvement with An Implementation of The Standard Operating Procedure in Cadaveric Eye Retrieval in District General Hospital, Matale, Sri Lanka

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## Abstract

According to World Health Organization in the year 2010, the global prevalence of blindness was 39 million. Out of the causes of blindness 4% is due to corneal opacity. Corneal transplantation is often a remedy for getting the vision back of patients with damaged corneas. Cadaveric eye retrieval plays a major role in this regard. We have observed suboptimal standards on many occasions in the cadaveric eye retrieval process in District General Hospital, Matale. We noticed a knowledge gap in the eye retrieval process among eye retrieval technicians, medico officers, nursing officers, judicial medical officers, and inquirers into sudden deaths. We identified several gaps in the selection of the donors, process of eye retrieval, and legitimacy. With extensive research, we introduced a printed form to be filled by the eye retrieval technician, the medical officer who certifies the death in the ward, the inquirer into sudden death, or the judicial medical officer in a case of an inquest. The aim of the implementation of this form and the standard operating procedure is to ensure that all activities involving human cadaveric eye retrieval are performed for the purposes of human health benefit, disease prevention, and improving the health system in a legitimate way. We suggest implementing this form and the standard operative procedure in the whole country so that the institutions and the eye technicians adhere to the duties specified in the standard operating procedure leading to improvement in the desired quality of the eye retrieval process and provide providing guidance to stakeholders in the process of cadaveric eye retrieval.

**Keywords:** Cadaveric eye retrieval, standard operating procedure, donor exclusion criteria

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## Introduction

According to World Health Organization in 2010, the global prevalence of blindness was 39 million.[1] Out of the causes of blindness 4% is due to corneal opacity.[1] Corneal transplantation is often a remedy for getting the vision back of patients with damaged corneas. Cadaveric eye retrieval plays a major role in this regard. Even with the rapid developments in surgical techniques and instruments, corneal blindness remains a prevalent global health issue. There is a significant scarcity of good-quality corneal grafts. More than 2 million people around the world since 1961 had cadaveric corneal transplantations.[1] In Sri Lanka, the Eye Donation Society (EDS) and the National eye bank

(NEB) are the major two organizations involved in the retrieval and supply of cadaveric eyes.[2] There are eye retrieval technicians (ERTs) placed all around the country engaged in this process. Since 1961 after its establishment, EDS has provided 118,000 corneas to the patients.[1] EDS and NEB have done corneal donations to a local hospital for patients. About 53,830 corneas are exported by EDS and NEB for transplantations in 57 countries all over the world and 30,000 corneas are supplied for research purposes.[2] The successful outcome of the corneal transplant depends on many factors such as surgical and clinical expertise, the quality of the tissue, and the steps taken to minimize the risk of

disease transmission from donor to recipient. Corneal screening, preservation, corneal storage, and prevention of systemic disease transmission from donor to recipient have been crucial in shaping the policies of the eye banks across the world. Standard Operational Procedures (SOPs) and essential instructions for retrieval of eyes have been developed by organizations in many countries, aiming to improve the quality and minimize the health hazard. In Sri Lanka, EDS and NEB had developed guidelines for eye retrieval and legal validity was granted by the Corneal Graft Act no 38 of 1955.[4]

### Objectives

The aim of the implementation of this form and the SOP is

1. to improve the standards in the cadaveric eye retrieval process and
2. to ensure that all activities involving human cadaveric eye retrieval are performed for the purposes of human health benefit, disease prevention, and improving the health system.

### Discussion

We have observed suboptimal standards on many occasions in the cadaveric eye retrieval process at District General Hospital, Matale. In Sri Lanka, although the legal guide and list of contraindications for cadaveric eye retrieval have been provided by the Eye donation society (EDS), follow-up of those by eye retrieval technicians (ERT) was not observed. According to the guideline provided by the EDS, Eye retrieval cannot be performed in several pathological conditions. The usual practice in Sri Lanka is the identification of the exclusion criteria by the ERT. Eye retrieval by the ERT without taking proper permission from the relevant authority to retrieve eyes from legal cases was observed. Moreover, the quality control of grafts in Sri Lanka was discovered to be an essential issue, such as infected donor cornea.[5][10] Knowledge gap was also observed in ERTs, nursing officers (NO), Medical officers (MO), inquirers into sudden deaths (ISDs), and some judicial medical officers (JMOs) on the cadaveric eye retrieval process.

We identified several gaps in the selection of the donors, process of eye retrieval, and legitimacy. To prevent similar issues SOPs provided by regulatory authorities in action can be identified in many countries.[7] At DGHM a multidisciplinary team consisting of a consultant Eye surgeon, consultant microbiologist, director of the hospital and the consultant JMO met on several occasions to discuss the issues in the process of eye retrieval and to find

remedies for those. In many developed countries, the standard protocol is MO gives the permission to ERT to retrieve the eyes of a descendant who does not have diseases that are contraindicated for eye retrieval.[8] This authorisation of the designated officer would include the following, whether death has been established, whether the donor had expressed a wish for and consented to the removal of tissue or consent has been obtained from the senior available next of kin of the deceased, and whether referral of the donor to the Coroner is required, whether the coroner has provided authority for the removal of the eyes.

With extensive research, we introduced a printed form to be filled by the ERT, MO who certifies the death in the ward, or ISD or the JMO in case of an inquest. The aim of the implementation of the form and the SOP is to ensure that all activities involving human cadaveric eye retrieval are performed for the purposes of human health benefit, disease prevention, and improving the health system. The exclusion criteria for eye retrieval were selected based on many organisations from developed countries.[6] In a ward death without an inquest, the MO who certifies the death will give permission to the ERT on descendants without exclusion criteria for eye retrieval. So that descendant with exclusion criteria for eye retrieval would not be selected even though the descendant or the next of the kin had consented to do so. This printed form has all the contraindications for eye retrieval in English and Sinhala language.

This form is in compliance with the Corneal Grafting Act, No. 38 of 1955, and paragraph 6 of the act describes the power of giving the authority of eye retrieval by a designated person of the hospital.[4]

In a case of an inquest where the ISD would release the dead body without an autopsy, the ISD would give permission to the ERT for eye retrieval on decedents without exclusion criteria by referring to the printed form which has exclusion criteria. In an autopsy, the JMO will give permission to ERT for the eye retrieval on descendants' who do not have diseases or conditions that are contraindicated for eye retrieval.

This form is also in compliance with the circular issued by the secretary to the ministry of health on 14th October 2010 as the general circular no 01-37/2010 gives detailed procedure which has to be followed in organ retrieval in an inquest.[9]

To improve knowledge among MOs, NOS, and ISD separate lectures were conducted. We organised special lectures with the assistance of the infection control unit of the hospital for ERT to develop knowledge and skills to maintain asepsis on cadaveric eye retrieval. Planned interventions were implemented. Administrative clearance was obtained from the Director of DGHM.

Gradually the members who got involved in the process of retrieval of cadaveric eyes started using the standard format. It was observed that there was an improvement in the knowledge regarding eye retrieval and legal requirement in all categories. ERT, NOs, Mos, and ISD expressed gratitude for involving and upgrading their knowledge. They expressed their enthusiasm to continue this practice. ERT was adopted well for aseptic techniques in eye retrieving. Knowledge, skills, and attitude improvement were observed in ERT.

### Conclusions

Due to the SOP, we observed there was a reduction in the retrieval of the eyes that were not suitable for retrieval due to the time lag between death and retrieval of eyes. Inappropriate Donors could be identified by the list of exclusion criteria. We also observed the proper process of obtaining authorisation from the ISD and JMO in cases of an inquest.

We suggest implementing this form and the standard operative procedure in the whole country so that the institutions and the eye technicians adhere to the duties specified in the SOP with improvement of the desired quality of the eye retrieval process and to provide guidance to stakeholders in the process of cadaveric eye retrieval.

### Disclosure statement

**Conflicts of Interest:** The authors declare that they have no conflicts of interest.

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## Annexures

### Annexure 1: Standard Operating Procedure (SOP)

#### Standard Operating Procedure (SOP) to be followed by the medical officer in ward-deaths during cadaveric eye retrieval

1. Death has been established according to the relevant act
2. The manner of death of the deceased was on natural disease circumstances
3. The donor had expressed a wish for and consented to the removal of tissue or Consent has been obtained from the senior available next of kin of the deceased
4. Referral of the donor to the ISD / Coroner is not required
5. The deceased has no disease or condition that is contraindicated for eye retrieval for transplantation based on the list of contraindications on the printed form
6. If the above 1,2,3,4 and 5 are fulfilled the medical officer who treated and certified the death informs the eye retrieval technician for cadaveric eye retrieval

7. In a death where an inquest is held the ISD or JMO informs the eye retrieval technician for cadaveric eye retrieval if the 1, 3, and 5 are fulfilled

**Annexure 2: The Form prepared**

QMU/21/07

මාතලේ මහා රෝහලේදී මෘතදේහ වලින් ඇස් ලබා ගැනීමට අනුමැතිය ලබා ගැනීම

මියගිය පුද්ගලයාගේ තොරතුරු. (අක්ෂි තාක්ෂණ නිලධාරියා විසින් සම්පූර්ණ කල යුතුය.)

- 1. මියගිය පුද්ගලයාගේ සම්පූර්ණ නම -.....
- 2. ජාතික හැඳුනුම්පත් අංකය-.....
- 3. වයස-....., 4. ස්ත්‍රී/පුරුෂ භාවය-.....
- 5. වාට්ටුව-..... 6. ඇඳ ඉහපත් අංකය: .....
- 7. මිය ගිය දිනය හා වෙලාව-.....

ඇස් දන් දීමට කැමැත්ත දුන් ඥාතියාගේ විස්තර(අක්ෂි තාක්ෂණ නිලධාරියා විසින් සම්පූර්ණ කල යුතුය.)

I. සම්පූර්ණ නම.....

ජාතික හැඳුනුම්පත් අංකය-.....

ලිපිනය-.....

මියගිය පුද්ගලයාට ඇති ඥාතිකම: .....

අත්සන-.....

II. සම්පූර්ණ නම-.....

ජාතික හැඳුනුම්පත් අංකය -.....

ලිපිනය:.....

මියගිය පුද්ගලයාට ඇති ඥාතිකම -.....

අත්සන-.....

**A. හදිසි මරණ පරීක්ෂණයක් හෝ පශ්චාත් මරණ පරීක්ෂණයක් නොමැතිව, වාට්ටුවේ වෛද්‍යවරයා විසින් මරණයට හේතුව ලබාදෙන අවස්ථාවලදී. When there is no inquest or autopsy, and a medical cause of death is given by the medical officer at the ward. (මරණ ප්‍රකාශය සම්පූර්ණ කල වෛද්‍යවරයා විසින් සම්පූර්ණ කල යුතුය. To be filled by the medical officer of the ward who fills the death declaration form)**

මරණයට හේතුව. Cause of death: .....

වෛද්‍යවරයා විසින් ලබාදී ඇති මරණයට හේතුව, අක්ෂි දානය සඳහා බාධාවක් නොවන රෝගයක්වේ. The cause of death given by the medical officer is not contraindicated for eye donation.

ඔව්/yes නැත/no

වෛද්‍යවරයාගේ සම්පූර්ණ නම. Full name of the medical officer: .....

නනතුර. Designation -.....

වෛද්‍යවරයාගේ අත්සන . Signature-.....

**B. හදිසි මරණ පරීක්ෂක විසින් පශ්චාත් මරණ පරීක්ෂණයක් නොමැතිව මරණයට හේතුව ලබා දෙන අවස්ථාවේදී. (හදිසි මරණ පරීක්ෂකවරයා විසින් සම්පූර්ණ කල යුතුය)**

හදිසි මරණ පරීක්ෂණ අංකය-.....

මරණයට හේතුව-.....

හදිසි මරණ පරීක්ෂක විසින් ලබාදී ඇති මරණයට හේතුව, අක්ෂි දානය සඳහා බාධාවක් නොවන රෝගයක් වේ: ඔව්/yes නැත/no

හදිසි මරණ පරීක්ෂක වරයාගේ සම්පූර්ණ නම-.....

හදිසි මරණ පරීක්ෂක වරයාගේ අත්සන සහ නිල මුද්‍රාව: .....

**C. පශ්චාත් මරණ පරීක්ෂණයක් ඇති අවස්ථාවේදී (විශේෂඥ අධිකරණ වෛද්‍යවරයා හෝ නීති වෛද්‍යවරයා විසින් සම්පූර්ණ කල යුතුය. )**

පශ්චාත් මරණ පරීක්ෂණ අංකය-.....

මරණයට හේතුව-.....

අධිකරණ වෛද්‍යවරයා විසින් ලබාදී ඇති මරණයට හේතුව, අක්ෂි දානය සඳහා බාධාවක් නොවන රෝගයක් වේ: ඔව්/ yes නැත /no

විශේෂඥ අධිකරණ වෛද්‍යවරයා හෝ නීති වෛද්‍යවරයාගේ සම්පූර්ණ නම-.....

විශේෂඥ අධිකරණ වෛද්‍යවරයා හෝ නීති වෛද්‍යවරයාගේ අත්සන සහ නිල මුද්‍රාව-.....

ඇස් දන්දීමට බාධාවක් වන මරණයට හේතු, මෙම පෝරමයේ පිටුපස මුද්‍රණය කර ඇත. (contraindicated causes of death for eye retrieval are printed on the back of this form)

**Donor Exclusion Criteria**

Eyes cannot be taken if the donor has had one of these diseases

**General exclusion**

- 1. Death of unknown cause
- 2. Above 75 years
- 3. If the time to retrieve is more than 8 hours after the death of the donor

**Infectious diseases**

1. Hepatitis, syphilis, slow virus infection, AIDS, ARDS, HTLV,
2. Active malaria
3. Tuberculosis
4. Rabies
5. Creutzfeldt – Jacob’s disease (Mad Cow disease)
6. Leprosy
7. Encephalitis
8. Endocarditis
9. Meningitis-active or of unknown origin
10. Progressive multifocal leukoencephalopathy
11. Subacute sclerosing panencephalitis
12. Reye’s syndrome
13. Congenital rubella
14. Smallpox
15. Typhoid- active
16. All conditions of fungal and bacterial disease
17. History of sepsis
18. Inflammatory disease (infected wounds)

**Haematological malignancy**

1. Hodgkin’s disease
  2. Leukaemia
  3. Lymphoma
  4. Lymphomatoid granulomatosis
  5. Lymphosarcoma
  6. Myeloma
  7. Myeloproliferative diseases
  8. Polycythaemia Vera-primary
- (Other cancers acceptable except disseminated melanoma)

**Neurological disorders**

1. Debilitating, Degenerative, Neurological disease
2. Any evidence of dementia or recent unexplained neurological symptoms.
3. Alzheimer’s disease
4. Parkinson’s disease
5. Multiple sclerosis
6. Creutzfeldt–Jacob’s disease in donor/ immediate family member
7. Motor neuron disease.

**Risk behaviour**

1. Intravenous drug user
2. Man, who had sex with another man within the last 5 years
3. A person who has had sex with HIV suspected person / Person who has multiple sexual partners
4. Tattoos or body piercings (within 4-6 months)

**Eye disorders, infections, and surgery**

1. Ocular or intraocular infections-active at the time of death.
2. Malignant tumours of the eye.
3. Corneal disorders
4. Corneal opacity, scarring, or pterygium

5. which involves the central area of the corneal button
6. Corneal surgery  
(Surgery/laser treatment for disorders other than corneal acceptable. Other eye disorders e.g. - cataract, glaucoma, AMD, retinopathy acceptable)

**Other**

1. Autoimmune disease
2. Serious illness of unknown aetiology
3. Prolonged corticosteroid therapy
4. Exposure to a toxic substance
5. Treatment with human pituitary derived growth hormone
6. More than 20% burn donor
7. Biopsy to rule out a tumour
8. Past history of blood transfusion (several times)
9. Eye donor is a recipient of a human organ or tissue transplant