Cornea donation

Module — 11

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CNDO
Nationaler Ausschuss für Organspende
Comité National du don d'organes

swiss transplant

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The term "organ donation" also includes tissue donation wherever appropriate.

1.0
Introduction

1.1 Objective

The aim of this module is to define minimum national standards for the cornea donation process – from identifying potential cornea tissue donors to handing over the transplants to the cornea bank. The following module provides a basic foundation for training the specialist medical personnel working in this area at the contracted hospitals with accredited intensive care units. Swisstransplant has received the mandate from the Swiss Conference of the Cantonal Ministers of Public Health (GDK / CDS) to develop and provide guidelines with regard to the organ and tissue donation process for these hospitals.

1.2 Scope of application

These recommendations are intended for all persons who work in the area of cornea tissue donation and who cooperate with Swisstransplant. They help to improve the quality and safety of the process, ensuring the optimal level of care and to prevent the transmission of diseases. Health protection, transparency of the process, traceability of donations and respect for the dignity of the deceased person and their relatives take first priority.
The recommendations presented here serve as a basis for introducing or updating processes and structures for cornea donation among all of the institutions involved. The obligations of the cornea banks with respect to controlling, handling, conserving, storing and distributing corneas will not be covered here, however.

This document complies with the following requirements:
- Federal Act of 8 October 2004 on the Transplantation of Organs, Tissues and Cells, SR 810.21 (status as of 1 February 2021)
- Federal Ordinance of 16 March 2007 on the Transplantation of Human Organs, Tissues and Cells (Swiss Transplantation Ordinance), SR 810.211 (status as of 15 November 2017)
- Guidance issued by the Federal Office of Public Health (FOPH) concerning Articles 13, 14, 16–18 and 51 of the Swiss Transplantation Ordinance on the Handling of Organs, Tissues and Cells for Transplantation of 15 November 2017
- "Mehr Organe für Transplantationen" (More organs for transplantations) campaign (www.admin.ch), FOPH, status as of 14 September 2021
- Service agreement between the Swiss Conference of the Cantonal Ministers of Public Health (CMPH) and the Swisstransplant national foundation covering the provision of services by Swisstransplant within the scope of the National Committee for Organ Donation (CNDO) for the years 2017–2021
- Guide to the quality and safety of tissues and cells for human application, 5th edition; European Directorate for the Quality of Medicines and HealthCare (EDQM)
- Minimum Medical Standards Revision 5, European Eye Bank Association (EEBA)
- Directive 2004 / 23 / EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells

Similar to the organ donation process, tissue donation and therefore cornea donation is carried out on a free, anonymous and voluntary basis.
The legal and ethical principles involving organ and tissue donation are covered in the Swiss Donation Pathway (SDP) – Module 1 – Donor recognition: legal basis and relevance in practice.

Please note the following:
This document presents requirements and recommendations:
Requirements are of a binding nature and worded with "must" expressions in order to meet the requirements of the Swiss Transplantation Act.
Recommendations are for information purposes, of a facultative nature and worded with "can" or "may" expressions.

1.3 Duties and responsibilities

Duties and responsibilities may be managed differently depending on the internal organisation of the various institutions.
Each hospital or institution can decide for itself the FOPH-approved eye bank (hereinafter the "cornea bank") with which it would like to enter a partnership. This partnership requires a contractual agreement.
Both the donation networks and Swisstransplant are to be informed of the decision in order to ensure cornea donations in Switzerland are monitored.
The specific responsibilities, from identifying the donor through to procurement, must each be handled by the personnel trained specifically for the individual processes. In cases of multi-organ procurement, parts of the cornea donation process are managed by the donor coordination unit. An extension of the local coordinators' tasks for the detection, interviewing and caring for relatives, checking contraindications (see appendix) and donor treatment should be evaluated in a further step to all cornea donations (intensive care units, all departments) should be examined. According to art. 47 of the Ordinance on Transplantation, local coordinators are responsible for ensuring that the donation procedures within the hospital, from the identification of potential donors to the removal of corneas, are properly initiated and coordinated. The coordinators are also responsible for quality assurance and monitoring procedures.
The donation is based on detailed documents that provide a comprehensive description of the various stages of the process. These documents must be integrated into the hospital's quality management system (QMS).
Specially trained personnel (donor coordination unit in the case of multi-organ procurement) are responsible for donor recognition and assessing contraindications for corneal tissue donation. A minimum standard has been defined (document 1) in cooperation with the cornea expert group at Swisstransplant.

1.4 Background information on cornea transplantation

The first cornea transplantation was performed in 1905 by the Austrian ophthalmologist Eduard Zirm. Today, it is one of the most frequently performed transplantation procedures around the world.

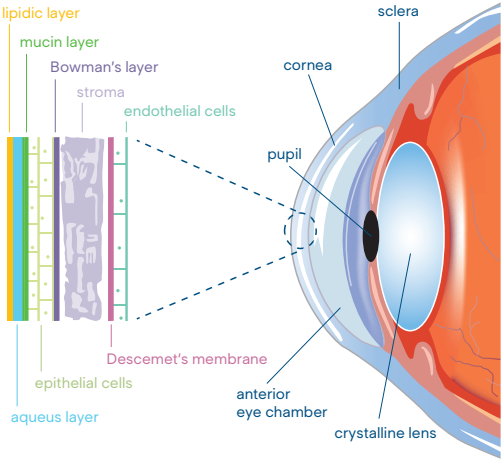
Around 900 operations of this type are performed in Switzerland alone each year. Less than half of the corneas used originate from Swiss donors, and the need for corneas is growing each year. (Source: Figures on tissue donations and transplantation in Switzerland, Federal Office of Public Health, status as of 14 September 2021).

2.0

Fundamentals for cornea tissue donation

2.1 Anatomy of the cornea

The cornea is the transparent window in the anterior part of the eye. It protects the eye and is both transparent and refractive.
The cornea has three main layers: the epithelium, stroma and endothelium. Human leukocyte antigen (HLA) compatibility is only necessary in rare cases because the cornea is avascular and is therefore easier to use in comparison to organs.



2.2 Cornea retrieval

The cornea can either be taken from an organ donor or deceased donor (according to recommendation by banks, between 24 and 48 hours post mortem). A more detailed description of the donation procedure is covered in chapter 3.
When it is received at the cornea bank, the corneal tissue is subject to a quarantine in preparation for the mandatory serological, morphological and microbiological examinations.

The quarantine normally lasts eight days but may differ in urgent cases. When evaluating the cornea, measuring the cell density is particularly important.
Once the various tests have been completed, the cornea has to be delivered to the transplantation facility within one month, according to the cornea bank requirement.

2.3 Indications and types of transplantation

The main indications for transplantation are corneal dystrophy (keratoconus), Fuchs' dystrophy (cornea guttata), infectious keratitis, trauma, burns and secondary damage from infections.
Different transplantations can be performed depending on the disease (anterior, endothelial or full-thickness transplantation).

Even though a corneal transplantation is not a matter of life and death, it can substantially improve patients' quality of life and allow them to return to their normal social and professional lives. The transplantation is often well tolerated and may even last for more than 20 years.
The underlying disease is the main determining factor for achieving clear graft survival and avoiding rejection. In cases where there is a high risk of rejection, systemic immunomodulators must be administered temporarily.

2.4 Quality assurance

The use of donor tissue and cells in the human body can lead to side effects and to the transmission of diseases. This risk can be greatly reduced by rigorously evaluating the donors and examining the donated corneas according to specific and current requirements.
All donation criteria as well as all preparatory stages for the cornea donation (from identifying the donor to delivering it to the corneal bank) must be handled and assessed by appropriately qualified and trained personnel.
Extensive knowledge of the procedure is essential for ensuring that donors and their relatives are treated in the best way possible.
The responsible personnel must be familiar with the resources used by the various facilities in order to complete all of the necessary steps.
Ideally, the donation process is monitored by donor coordinators, as they are already wellversed in the matter.
A separate document must always be created for each donor to validate all steps of the corneal procurement – from assessing potential contraindications to delivering the corneas to the cornea bank.
Each facility should define a Standard Operating Procedure (SOP) that precisely describes the individual stages of the donation process.
We recommend that each hospital maintains a secure and confidential file documenting all deceased patients. This makes it possible to assess the number of potential donors and their suitability for the corneal donation, including when no active search for a donor is underway.
To comply with quality and safety standards, an appropriate system must be in place to guarantee traceability.

3.0

Cornea donation process

3.1 Deceased patients identification

Deceased patients can be identified as potential candidates for cornea donation in several different ways:

- Systematic search: staff who are responsible for identifying potential cornea donors seek out deceased patients with the support of hospital-specific systems, such as electronic patient records, case history etc.
- Active reporting of potential cornea donors by the medical personnel who had looked after the deceased patient
- Reporting by personnel in the wards or morgue

The real capacities and options for identifying potential donors will depend on the human resources available at the various institutions.

3.2 Assessing suitability for cornea donation

After identifying a deceased patient, the process for assessing their suitability for cornea donation has to begin.

3.2.1 Assessing contraindications

Swisstransplant togehter with representatives of the cornea banks have drawn up a list of minimum contraindications (document 1). The individual cornea banks may have more stringent requirements, however.
Based on the patient's medical records, a comprehensive and thorough assessment of the contraindications must be performed. Additional information can be added by the ward doctor, attending physician, the family or other parties in order to obtain a sound conclusion. If doubts arise in the course of the assessment, the partner cornea bank can be contacted to determine the suitability of the donor. In the case of multi-organ retrieval, document 2 (Cornea-DIF-SOAS multirorgan retrieval) has to be used.
As explained in the annex, the assessment of contraindications must include supporting written documentation from the respective institution. This document, meanwhile, is based on the Swisstransplant list of contraindications.
In contrast to most organ transplantations, a corneal transplant is not necessary for survival. For this reason, extra attention should be given to the selection of donors.
We recommend checking contraindications and assessing the deceased person's suitability for cornea donation by two different persons. The second examination should ideally take place before the procurement and always before approving the cornea for the transplantation.

If no contraindications have been identified, the presumed willingness of the deceased person to be a donor will be assessed (chapter 3.3). The person responsible shall ensure that the donor's body is not taken from the funeral service provider before the retrieval of the cornea. The donor's body must be cooled following the recommendations of the cornea bank, as this can affect the quality of corneal transplantations.

3.2.2 Unnatural death

If the cause of death is considered unnatural, permission for the procurement is required by the judicial authorities. The process for obtaining this permission varies between the different cantons and institutions.

3.3. Assessing willingness for a cornea donation

For the medical personnel performing this assessment, trainings on communication and the cornea donation process are highly recommended.
If there are any written statements objecting to organ and tissue donation, the process is terminated.
If there is no written refusal to donation , the relatives are to be contacted. In such cases, the relatives' order or precedence must be observed as set out in Article 5 of the Swiss Transplantation Ordinance of 16 March 2007 (SR 810.211): spouse, registered partner, life partner; children, parents and siblings; grandparents and grandchildren; other persons who were close to the deceased person.
In case of consent, the relatives will be informed about the wishes of the deceased person and the donation process.
If no statement was made by the patient regarding organ and tissue donation, an enquiry must be made into their presumed consent.
Module II of the Swiss Donation Pathway addresses taking care of relatives and communication. Independent of a multi-organ donation process, the discussion with the donor's relatives can be conducted by phone. It is recommended that the phone call be documented in writing according to a set of guidelines (e.g. document 3).
The relatives should be contacted within a few hours of the patient's death to minimize the amount of time prior to retrieval of the corneas.
The possibility of the corneal donation and type of procurement should be explained during the interview (restoring the original appearance with closed eyelids has to be communicated). If necessary, the relatives can be allowed "monitored" counselling. During this discussion, the anamnesis can be completed as well. This can result in the identification of contraindications.
If the relatives object to the donation or cannot be reached, the process is stopped.

If they agree, a consent form for the cornea donation must be completed (Swisstransplant document on informed consent, document 4 or the respective institution's own document). This document must contain the following information:

- Date and time when willingness to donate was assessed
- Name of contacted person and relationship to the deceased person
- Name and function of the person who conducted the consultation
- The decision on authorised retrieval

In addition, the relatives are provided with the contact details of the person responsible for addressing any questions that may arise.
Regardless of the outcome of the interview, the relatives will be thanked and assured that their decision will be respected.

3.4 Retrieval of the cornea

3.4.1 Personnel involved

The procurement must be performed by an ophthalmologist or a person trained specifically for this operation. We recommend having two people retrieve the cornea to guarantee proper identification of the deceased person, to help move the donor's body for the required assessments and to ensure the procurement is aseptic.

3.4.2 Retrieval room

The cornea must be retrieved under aseptic conditions in a location suitable for this purpose. In the case of multi-organ donors, it can also be performed directly in the operating theatre. The procurement should be performed in a room where the privacy of the deceased person is strictly protected.
For hygienic and ethical reasons, no other deceased persons should be in the immediate vicinity (adjacent table).

Equipment and requirements for the room (see EDQM guide, Ch. 6.3 and 16.3.3):
- Running water and waste disposal device
- Work surface, trolley, adequate lighting and ventilation to perform the procurement
- Compliance with hospital hygiene standards

3.4.3 Preparation for cornea retrieval

It is important to promptly notify the specialist medical personnel responsible for handling the donor's body (morgue, operating theatre, wards etc.). This prevents the possibility of the funeral service collecting the donor's body. The time and location of the procurement can also be scheduled at this point.

Before the procurement, the responsible personnel must check the following items in the file and / or that the appropriate documents are on hand:
- No contraindications found
- Natural death or permission from the relevant legal authority in cases of unnatural death
- Consent for the donation

Planning and preparation for the procurement:
- If an autopsy is required (medical or judicial), take measures to prioritize the procurement. The taking of blood samples and the cornea retrieval should ideally be performed before the autopsy to reduce the risk of bacterial contamination and to enable serological blood tests

- Planning when the necessary parties will be present
- Scheduling the time for the procurement
- Selecting and preparing the location for the procurement
- Organizing any required transport of the donor's body
- Depending on the requirement of the institution, a premortal blood sample from the laboratory may be used for all or some of the required serological examinations (performed less than seven days before death and provided that no surgical procedure or event with a risk of contamination has occurred in the meantime).
- Request laboratory analyses (see annex and document 5)
- Check and prepare the instruments for the procurement and provide a retrieval kit for the procurement
- Prepare the transport packaging as recommended by the partner cornea bank

3.4.4 Cornea retrieval

There are two techniques for the retrieval: in situ cornea retrieval (corneoscleral disc) or enucleation. Which of the two techniques will be applied has to be discussed with the partner cornea bank.
The retrieval is performed by a person with the appropriate training. We recommend having a second person provide assistance, complete the documentation in the file and ensure an aseptic procurement process.
The person who performs the retrieval wears a mask, protective glasses, a surgical hood, surgical gown and sterile gloves. All persons present are at least to wear surgical masks and hoods.
For each donor, a separate document must be prepared and include the information listed above (form for cornea retrieval).

All personnel must handle the donor's body with dignity and care. The person performing the retrieval is responsible for restoring the original anatomical state.
After the retrieval, it is recommended that an information document be included with the donor's body for the funeral home. This document states that the procurement was performed, includes the contact details of the responsible persons and explains that bleeding may occur.

Determining the identity of the deceased donor

We recommend having two persons identify the donor by comparing the name, surname and date of birth on the identification wristband with the information in the file (consent form for cornea retrieval, approval by judicial authority in case of unnatural death, documentation from the death register).
To document that the assessment was performed, the donor file must include a copy of the death certificate.
If there are any discrepancies, the process will be suspended until these items have been resolved. If they remain unresolved, the process must be stopped.

Examining the body surface

This assessment is mandatory and must be performed according to the applicable recommendations. Any suspicious lesion must be reported to the cornea bank. Special attention must be given to the examination of the eyes in order to identify any local contraindications.

Blood sample

Swisstransplant lists the blood tests that must be performed (annex and document 5) and which may also need to meet the cornea bank's additional requirements. The blood sample must be performed within 24 hours after the time of death to ensure the quality of the results. Taking a post-mortem blood sample is not always simple. We recommend taking blood samples before retrieval of the cornea.
The usual method here is infraclavicular, intracardiac or femoral puncture. The person responsible for retrieving the cornea must possess the necessary expertise and ability to perform these techniques.
Respecting the dignity of the deceased person is crucial, which is why blood samples must be taken with the same degree of care as with a living person. The surgical preparation of veins to simplify the collection of blood samples should be avoided.
To ensure good analytical quality of the post-mortem blood sample, centrifugation should be performed as soon as possible.
The collecting tubes are identified according to the agreement and assignment of duties between the hospitals and cornea banks and then submitted for analysis. The cornea bank is responsible for retrieving and assessing the results.
In rare cases in which a blood sample is unsuccessful and no premortal sample is available, the process must be stopped.

In situ cornea retrieval (example; the cornea bank's protocol applies)

Protocol for the procurement
- Flush the right and then the left eye with 0.9% NaCl solution
- Wipe the eyelids, periorbital region on both sides, frontal bone, zygomatic bone and nostrils with betadine soap; rinse with physiological saline solution and allow to dry
- Disinfect the eyelids, periorbital regions on both sides, the frontal bone, the zygomatic bone and the nostrils with aqueous 5% betadine ophthalmic solution (can be made with 10% solution of Betadine Dermicum and 0.9% NaCl in 1:1 dilution)
- Disinfect both eyes twice, first the right and then the left, with 5% Betadine and allow a contact time of 2 minutes; flush the conjunctival sac of both eyes with 0.9% NaCl solution
- Cover with the sterile sheet
- Procedure for the right eye
- Apply the eyelid retractor
- Instil 5% Betadine and then flush with the 0.9% NaCl solution
- Incision of the conjunctival tissue: 360° sclerotomy with trepan and / or Castro scissors; retrieval along with circumferential scleral ring of 4 mm
- Detachment of the iris with forceps

– Place transplant in transport vessel (first check temperature, colour of fluid and expiration date)

Repeat the same procedure on the left eye; clean the face, close the eyes and restore the integrity of the donor

Enucleation (example; the cornea bank's protocol applies)

Protocol for the procurement
– Apply gentamicin antibiotic solution to the donor eye
– Eyelid retractor
– Using forceps from the sterile enucleation set, lift the conjunctiva and separate it in a circle around the cornea (peritomy); make sure that the cornea is not damaged by pulling too hard with the forceps
– The conjunctiva is separated bluntly from the sclera; this exposes the attachment points of the eye muscles; the muscles are gently pulled out using a hook
– The muscles are now severed successively on the outer edge of the squint hook
– Using a set of fixation forceps, gently lift up the bulbus
– Run blunt, closed enucleation scissors under the bulbus, opening it gently until there is noticeable resistance and sever the optic nerve approximately 1cm in front of its point of attachment; the bulbus can now be retrieved and placed in one of the plastic containers with NaCl / Gentamicin solution
– When harvesting the bulbus, the instruments must always be placed temporarily back in the enucleation set when they are not being used to prevent any contamination
– A plastic ball is placed in the eye cavity of the donor and the eyelids are closed with two recessed suture buttons; the retrieval is now complete; alternatively, the eyelids can be closed with adhesive
– Repeat the same procedure on the other eye

Labelling, packing and transport

After the procurement, the corneas must be packed, labelled and sent to the cornea bank. For transport purposes it is advised to first package the tissue in a sterile and sealed container with the appropriate transport solution and then in secondary packaging (plastic bag etc.) and finally in outer packaging (sturdy cardboard or similar). The label identifying the corneas must be applied to the first layer of packaging.
The bulbi that have been retrieved are sent to the eye bank for preparation as soon as possible (ideally within the next hour, no later than six hours, as the quality of the corneas will have already begun to deteriorate considerably).
Each cornea bank has its own recommendations for packaging and receiving the corneas. The bank is responsible for anonymising the individual retrievals.

3.5 Follow-up after cornea retrieval

The person responsible for the donation at the hospital can be contacted by the relatives if desired and offers them support following the procurement.
After the donation, the internal procedure at the respective hospital for handling the deceased person applies.
Overview of the contents of the donor file for ensuring the traceability in accordance with the internal procedures of the institution and the cornea bank:

- Form for examination of contraindications (e.g. Contraindications Cornea Switzerland practical guidance, see annex)
- Consent form
- Approval form from the judicial authority in case of an unnatural death
- Form for scheduling and procedure of the procurement
- Copy of the death certificate

The documents must be kept for 20 years.

Main steps following the procurement:

- Notify the cornea bank about the retrieval
- Note the cornea retrieval in the patient file
- Enter the information concerning tissue in SwissPOD (by responsible coordinator)
- Complete respective hospital's internal deceased patient document
- Send thank-you letter to the donor's relatives (recommended)
- Furnish materials and reprocess instruments if necessary, organize and clean equipment

4.0

Other particularities

4.1 Cornea retrieval as part of organ procurement process

We recommend having the corneas retrieved directly after the multi-organ procurement procedure in the operating theatre.
The additional serological examinations for the cornea retrieval must be requested (HCV-RNA and other examinations according to recommendations of the partner cornea bank).
To simplify the procurement and improve quality, it is advisable to complete these serological tests in combination with those used for the organ donation.
The cornea DIF (document 2) must be completed by the organ procurement coordinator and included in the Swiss Organ Allocation System (SOAS). A thank-you letter for both the organ and tissue donation (corneas) is written.

4.2 Information and training

The personnel in the ward should also familiarize themselves with the topics surrounding cornea donation, as each deceased patient is a potential candidate for cornea donation. It must be explained to all employees why it is important to close the eyes, when cooling must begin and how the documentation must be prepared in the file.
As with other organ donations, cornea donations make it necessary to conduct information and awareness campaigns in line with the motto: "Everyone is a potential donor." The aim of these campaigns should be to simplify the decision-making process.

5.0

Summary of the cornea donation process

Staff trained in all process steps with proof of training

- Identification of the deceased patients
- Evaluation of contraindications to corneal donation
- Obtaining the presumed will of the patient
- Legal decision in case of unnatural death
- Organisation of the collection
  (Anonymisation according to the bank's instructions)
- Verification of the identity and appearance of the body
- Serological tests of the donor
- Retrieval of the cornea
- Restoration of bodily integrity
- Packing and transport of the cornea
- Process after collection
  (Thank you letter, SwissPOD, classification, material preparation ...)

Cornea bank approved by FOPH

- Verification and packaging of the cornea by the cornea bank
- Delivery of the cornea by the cornea bank to the transplant centre

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Version 1.0

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References

1. "Mehr Organe für Transplantationen" (More organs for transplantations) campaign (www.admin.ch), Federal Office of Public Health, status as of 14 September 2021
2. Federal Act of 8 October 2004 on the Transplantation of Organs, Tissues and Cells, SR 810.21 (status as of 1 February 2021)
3. PLDO recommendations on cornea donation 2014/Recommandations du Programme Latin du Don d'Organes 2014
4. Guide to the quality and safety of tissues and cells for human application, 4th edition European Directorate for the Quality of Medicines and HealthCare (EDQM)
5. Service agreement between the Swiss Conference of the Cantonal Ministers of Public Health (CMPH) and the Swisstransplant foundation covering the provision of services by Swisstransplant under the purview of the National Committee for Organ Donation (CNDO) for the years 2017–2021
6. Minimum Medical Standards Revision 5, European Eye Bank Association EEBA
7. Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells
8. Federal Ordinance of 16 March 2007 on the Transplantation of Human Organs, Tissues and Cells (Swiss Transplantation Ordinance), SR 810.211 (status as of 15 November 2017)
9. Figures on the donation and transplantation of tissues in Switzerland (www.admin.ch), Federal Office of Public Health
10. Guidance issued by the Federal Office of Public Health concerning Articles 13, 14, 16–18 and 51 of the Swiss Transplantation Ordinance on the Handling of Organs, Tissues and Cells for Transplantation of 15 November 2017

Documents

These documents can be downloaded from the Swisstransplant Extranet.

- Document 1: Swisstransplant Evaluation contraindications in cornea donation
- Document 2: Swisstransplant CORNEA-DIF-SOAS multi-organ retrieval
- Document 3: Swisstransplant recommendation on how to conduct telephone interviews with relatives of cornea donors
- Document 4: Swisstransplant consent form for cornea donation (informed consent)
- Document 5: Swisstransplant list of required laboratory tests in connection with cornea donations (cornea lab tests)

Changes

Date	Version	Changes
February 2023	1.1	Corrections
November 2021	1.0	Original Version

Annexe

Annex 1: Swisstransplant list of contraindications for cornea donation (Evaluation Contraindications Cornea Switzerland practical guidance)

Evaluation contraindications in Cornea donation Practical guidance

Ocular Tissue

Mandatory informations and examinations EEBA (minimal medical standard, operative from 01.02.2020)

Purpose
The purpose of these standards is to comment on the principles of donor selection, as laid down by the COMMISSION DIRECTIVE 2006/17/EC of 8 February 2006 describing the minimum information required for donor risk assessment and the sources of information that should be documented as part of the donor record.

Information required for donor risk assessment:
- Donor's identity and age
- Cause, time and circumstances of death
- Past and recent medical history
- Behavioural activity that increases the risk of transmissible diseases

Sources of information:
- Medical records
- Attending medical and nursing staff
- Family members or other relevant persons close to the deceased
- Family doctor
- Physical examination of the donor
- Post-mortem report if available and timely (when autopsy is performed)

Serological and microbiological testing mandatory for Switzerland
- HIV: HIV 1 + 2 Antibody and HIV 1 p24 Antigen or HIV PCR
- Hepatitis B: Anti-HBc, HBs Antigen. Anti-HBsAg only if Anti HBc positive. If Anti HBc-Test positive with HBs Ag negative, then a positive Anti-HBsAg or a negative HBV-PCR are required with careful clinical assessment.
- Hepatitis C: HCV Antibody, HCV-RNA (if doubtfull quantitative PCR)
- Syphilis: TPHA/TPPA
- Anti HTLV 1+2
- COVID PCR test, mandatory if pandemia

Recommendation and explanation of how to use this list:

The contraindication list should be used as each point should be checked for "in term of evidence of".

Absolute contraindications

	Explanation	yes	**no**	**unknown**
Death of unknown aetiology	Cause of death unknown, unless autopsy provides information on the cause of death after procurement and none of the general criteria for exclusion set out in the present section applies			
Exposition to toxic substances (lead, mercury etc.)	Ingestion of, or exposure to, a substance (such as cyanide, lead, mercury, gold) that may affect the quality of the ocular tissue, or may be transmitted to recipients in a dose that could endanger their health			
Age	Provided that corneas are examined to exclude those with inadequate endothelium, no upper donor age limit needs to be set, but other age-related corneal changes must be taken into account. The lower age limit is less certain and will depend on surgical demand			
Blood sample	Interval between cardiac arrest and obtention of a blood sample is over 24 hrs (except if pre-mortem blood, taken up max 7 days before death (see technical guidelines for ocular tissue EEBA))			

	Explanation	yes	no	unknown
Conservation criteria	It is recommended that corneal preservation occurs as soon as possible after death. All time intervals for each donor (death to enucleation and preservation) shall be recorded. Harvesting of the cornea has to be in between 24 hrs after death			
Behaviour leading to transmissible diseases	Evidence of any other risk factors for transmissible diseases on the basis of a risk assessment, taking into consideration donor social history (e.g. intravenous drug abuse, sexual promiscuity)			
Physical inspection of the body	Presence on the donor's body of physical signs implying a risk of transmissible disease(s), such as bruises, lacerations, scars, piercing, needle tracks not compatible with recent clinical history, fresh tattoos that may hide parenteral drug use, and signs of transmissible diseases such as Kaposi sarcoma, swollen lymph nodes, skin rashes, Jaundice of unknown aetiology, should be interpreted in the context of donor medical and social history			
Vaccine with an attenuated virus	Recent history of vaccination with a live attenuated virus where a risk of transmission is considered to exist			
Blood exposure accident	Evidence of any other risk factors for transmissible diseases on the basis of a risk assessment			

	Explanation	yes	**no**	**unknown**
Evidence of Jail for more than 4 days within the last year	Evidence of any other risk factors for transmissible diseases on the basis of a risk assessment			
Toxicomania (IV, IM, SC) donor and partner in the last 12 month	Evidence of any other risk factors for transmissible diseases on the basis of a risk assessment, taking into consideration donor social history (e.g. intravenous drug abuse, sexual promiscuity)			
Transplantation	Transplantation with xenografts			
Infectious diseases				
Viral	Acute viral encephalitis, disseminated or unknown encephalitis, meningitis, tropical spastic paraparesis			
	Progressive multifocal leukoencephalitis			
	Viral eye diseases (herpes, zona, varicella, HTLV)			
Rabies or contagion suspected	Ordinance on transplantation SR 810.211, Annex 5, Abs.2: Assessment of suitability for donation Exclusion of all people at risk of or suspected of being infected with the rabies virus Systemic infection not controlled at the time of donation, including bacterial diseases, systemic viral infections (such as rabies)			

	Explanation	yes	no	unknown
HIV, Hepatitis, HTLV	History, clinical or laboratory evidence of HIV or AIDS, acute or chronic hepatitis B (except in the case of persons with a proven immune status), hepatitis C and HTLV I/II, transmission risk or evidence of risk factors for these infections			
Congentital rubeola				
Jaundice of unknown aetiology				
COVID-19	**Ocular tissue donation: EEBA guideline for donor screening for SARS-CoV-2** The following table is intended to assist eye bank procurement and retrieval staff in their routine donor screening for SARS-CoV-2 and should be used in conjunction with local/regional/national exclusion and deferral criteria determined by competent health authorities, risk assessment instructions from the European Centre for Disease Prevention and Control (ECDC), and the selection/exclusion guidelines in the "ALERT UP-DATE: Coronavirus (COVID-2019) and Ocular Tissue Donation" of the Global Alliance of Eye Bank Associations (GAEBA). The social anamnesis of each potential donor should be included into each individual risk assessment to determine donor eligibility (e.g. includes close contact to COVID-19 infected persons, vaccination for COVID-19). Regarding procurement a sufficient disinfection of the ocular surface (e.g. with povidone-iodine) is important to inactivate/eliminate enveloped viruses.			

	Explanation	yes	no	unknown

SARS-CoV-2 status prior to death	test	donor eligibility
known/available	positive <14 days before death	not eligible
unknown/not available	nasopharyn-geal swab post-mortem*	
known/available	negative	eligible
known/available	positive >14 days before death	eligible 2 weeks after complete recovery and free of symptoms

*In this case an individual risk assessment is mandatory to decide whether the donor can be accepted or not. Postmortem nasopharyngeal swabs have not yet been validated. However, the result might be included in the risk assessment.

	Explanation	yes	no	unknown
Bacterial diseases				
Syphilis				

	Explanation	yes	no	unknown
Systemic infection	Systemic infection which is not controlled at the time of donation, including bacterial diseases, systemic viral (such as rabies), fungal or parasitic infections, or significant local infection in the tissues and cells to be donated. Donors with bacterial septicaemia (except for encephalitis and meningitis) may be evaluated and considered for eye donation but only where the corneas are to be stored by organ culture to allow detection of any bacterial contamination of the tissue			
Fungal diseases				
Fungal sepsis	Even under treatment (if there is a treated local fungal infection, just report it on the form)			

	Explanation	yes	no	unknown
Stay in a reported endemic area	Travel and exposure history and local infectious disease prevalence; in this context according to the Standards to the surveillance and epidemic intelligence actions of the European Centre of Disease Control it is important to investigate travel in high-risk regions when checking social anamnesis with regards to new or emerging communicable diseases such as the Ebola virus, Zika virus, new Corona virus (referred to as 2019-nCoV or Corona-Wuhan) etc. To look for a specific disease index for a country the UK Blood Services Geographical Disease Risk Index for example lists the current disease risks for specific countries (www.transfusionguidelines.org) Surveillance and disease data (europa.eu)			
Neurological pathology				
	Dura mater surgery <1992			
Autoimmune diseases	History of chronic, systemic autoimmune and/or inflammatory disease that could have a detrimental effect on the quality of the tissue to be retrieved; Example: multiple sclerosis, amyotrophic lateral sclerosis and others (ex. Lupus, Rheumatoid Arthritis, Syndrom Guillain-Barré, Alzheimer's Disease)			

	Explanation	yes	no	unknown
Treatment with extractive pituitary hormone <2000	Recipients of hormones derived from the human pituitary gland (such as growth hormones)			
Neurosurgical intervention <2000 or not documented	Persons that have undergone undocumented neurosurgery (where dura mater may have been used).			
Prion diseases	Creutzfeldt-Jakob or ESB and antecedents (Syndrome Gerstmann-Sträussler-Scheinker syndrome, kuru, family history of spongiform disease Stay for at least 6 months in G.B. between 1980 and 1996			
Degenerative neurological diseases	People with a history of rapid progressive dementia or degenerative neurological disease, including those of unknown origin, such as Alzheimer's Disease, multiple sclerosis, amyotrophic lateral sclerosis			
Subacute sclerosing panencephalitis				

	Explanation	yes	no	unknown
Neoplastic pathology				
Cancer type	Donors with malignant diseases can be evaluated and considered for cornea donation (not for donation of vascularized ocular tissues),except for those with retinoblastoma, haematological neoplasm (such as leukaemia, lymphoma, myeloma), and malignant tumours of the anterior segment of the eye (i.e. primary tumours such as conjunctival intraepithelial neoplasia, squamous cell carcinoma or malignant melanoma as well as metastasis in the anterior ocular segment from other primary malignant tumours). In the case of donors with malignant diseases and a potential risk of metastasis formation in the anterior ocular segment, a thorough slit-lamp examination of the globe or the corneo-scleral disc focused on possible metastasis must be undertaken in the eye bank			
Malignant metastatic melanoma	Malignant melanoma with known metastatic disease also excludes use of ocular tissue, including avascular cornea			
Liquid cancer	Malignant hemopathies: Myeloma, lymphoma, leukemia, Hodgkin cured <5 years, myelodysplasia			

	Explanation	yes	no	unknown
Treatment				
Corticosteroid therapy	As the treatment with immuno-suppressive agents may invalidate serological anti-body tests, a thorough risk assessment is recommended (re-evaluation of all donor sources of information, with particular focus on transmissible diseases). In case of uncertainty PCR / NAT testing for HIV, HBV and HCV might be helpful for a thorough risk assessment			

	Explanation	yes	no	unknown
Risk of hemodilution: see hemodilution algorithm EEBA for calculation (except if pre-dilution serum available <5 days)	If the donor has received transfusions or infusions within the last 48 h, the volumes must be recorded and an algorithm applied to assess plasma dilution. Plasma dilution may not exceed 50% if the testing procedures have not been validated for such plasma. According to the EDQM "Guide for the quality and safety of tissues and cells for human application" [3rd Edition 2017, pages 86 – 88] the following formula can be used to calculate the respective plasma dilution: Donor total plasma volume = 0,04 [l / kg] * donor body Infused colloids within 48 h pre mortem = colloids 48 h [l] Infused crystalloids within 1 h pre mortem = cristalloids 1 h [l] Total relevant infused volume = colloids 48 h [l] + crystalloids 1 h [l] Acceptable plasma dilution: Total relevant infused volume ≤ Donor total plasma volume or (colloids 48 h + crystalloids 1 h) [l]≤(0.04 [l/kg] * body weight [kg]). Explanation: Donor body weight (kg) × 0,04 (l / kg) serves as an estimate of the donor total plasma volume. The infused volume of colloids (within 48 h prior to death) and crystalloids (within 1 h prior to death) is summarized. Their total volume must be less than the estimated donor plasma volume. Eye banks may accept tissues from donors with plasma dilution of more than 50% only if the testing procedures used are validated for such plasma or if a pre-transfusion sample is available weight [kg]			

	Explanation	yes	no	unknown
Ocular pathology				
	Eye diseases and ocular surgery: congenital or acquired disorders of the eye (e.g. herpetic Keratitis), or previous ocular surgery, that would prejudice graft outcome (e.g. corneas with previous refractive surgery, or stromal scars, may be acceptable for posterior lamellar keratoplasty)			
	Previous Cornea, limbus or sclera transplant			
	Signs of uveitis or conjunctivitis (secretions)			
	Herpetic eye infection, ophthalmic shingles (active or old)			

If in the future there will be changes in the EEBA-guideline or in the guide to quality and safety of tissues and cells EDQM they will be integrated in the list.

Literature:

- EEBA minimal medical standard 01.02.2020 Downloads – EEBA
- Guide to the quality and safety of tissues and cells 4th edition 2019 EDQM (for the malignant melanoma)
- Ordinance on the transplantation of Human Organs, Tissues and Cells, SR 810.211, Switzerland (please note that this text does not exist in English), RS 810.211 – Ordonnance du 16 mars 2007 sur la transplantation d'organes, de tissus et de cellules d'origine humaine (Ordonnance sur la transplantation) (admin.ch)

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