



GAEBA Data Project – Data Definition Guide

This *Data Definition Guide* accompanies the *GAEBA Data Country Reporting Tool* (excel template). It is designed to assist each Association or independent collector to ensure data interpretation and translation is as accurate as possible at both the point of collection and the point of collation. It commences with an explanation of common supporting definitions prior to outlining the year-by-year data reporting requirements as outlined on the excel template.

For further information or support please contact the GAEBA Data Development Group.

Supportive Definitions (alphabetical order)

Adverse Reaction. An adverse reaction is the transmission of a communicable disease such as the following: fatal, life-threatening, results in permanent impairment of a body function or permanent damage to a body structure, or necessitates medical or surgical intervention, including hospitalization.

Anterior and Posterior Layers. A pre-cut cornea where both the anterior and posterior layers are present.

Anterior Lamellar Keratoplasty. Transplantation of the anterior stroma of the cornea.

Anterior Layer. Corneal stroma without endothelium. May include epithelium.

Cornea. Transparent anterior part of the outer fibrous coat of the eye bounded by an outer stratified epithelium and an inner monolayer of endothelial cells. The major refractive component of the eye.

Corneal Button. Cornea with scleral rim removed.

Corneoscleral Disc. Cornea excised with scleral rim which may include some conjunctiva.

Disposition. The final destination of tissue, including use for transplantation, education, research, or discard.

Distributing Eye Bank. The facility/organization that supplies tissue to another entity. They are responsible tracking recipient or consignee information, post op follow-up and reporting any adverse reaction to the source establishment and financial/invoicing as required.

Distribution. The process of allocating and distributing tissue for transplant, research or educational use. This process includes receipt of request, selection, inspection and release of tissue, to a consignee such as a surgeon, surgical centre or educational research centre. The principles of tracking, traceability and adverse reaction reporting will be maintained throughout the process of distribution.

Donor. A living or deceased individual who provides the source of tissue for transplantation, education, or research.

Donor Eligibility. The act of reviewing available medical records, serologic test results, hemodilution,

laboratory results, physician records, medical professional consultation, body exam, body identification, pre-recovery eye exam, records of equipment/reagents used in recovery, Donor Risk Assessment Interview, and recovery and tissue evaluation records to determine safety of tissue for surgical use.

Endothelial Keratoplasty. Transplantation of the corneal endothelium attached to a carrier.

Enucleation. Recovery of the whole eye from a deceased donor.

Eye Bank. An entity that provides or performs one or more functions involving ocular tissue from living or deceased individuals for transplantation, research, and/or educational purposes. See Eye Bank Functions.

Eye Bank Functions. Functions performed by an eye bank that subject the eye bank to local accreditation and/or auditing policies with their local association and/or governing bodies, including 1) recovery, 2) processing, 3) storage, 4) tissue evaluation, 5) donor eligibility determination, 6) Allocation, and 7) distribution.

Export. Tissue moved to another country or jurisdiction.

Graft. Tissues prepared for use in transplantation.

Hypothermic Storage. Stored in a solution at 2 to 8°C.

Import. Tissue obtained from another country/jurisdiction to service unmet need.

In-Situ Excision. Recovery of a cornea from a deceased donor.

Laser Assisted Keratoplasty. Corneal surgeries in which wound architecture is processed by laser.

Laser Assisted Anterior Keratoplasty. Anterior keratoplasty in which the lamellar and/or side dissection of the donor tissue is processed using a laser.

Laser Assisted Endothelial Keratoplasty. Endothelial keratoplasty (surgery) in which the lamellar and/or side dissection of the donor tissue is processed using a laser.

Laser Assisted Penetrating Keratoplasty. Penetrating keratoplasty in which the donor and recipient wound architecture are processed by laser.

Limbal Tissue. Tissue bridging the junction between the cornea and sclera.

Long Term Preservation. Cornea or corneal section stored in a solution that is designed to maintain tissue ultrastructure for greater than 14 days and up to five years depending on the technique. Viability is not maintained. Examples are ethanol and glycerin preservation. Other media, such as albumin, may be used in conjunction with ionizing radiation to preserve the tissue ultrastructure.

Moist Chamber. Whole eye stored at 2 to 8°C in a humid environment.

Organ culture storage: stored in a solution at +30 - +37°C for greater than 14 days and up to 30 days within solution which maintains viability of tissue. A deswelling of corneal tissue will be necessary before release for transplantation.

Posterior Layer. Endothelium on Descemet membrane with or without a supporting layer of posterior stroma.

Pre-Cut Tissue. Corneal tissue in which lamellar or vertical dissection has been processed for surgical use, by eye bank or other organization, prior to distribution for surgical use.

Preservation. The use of chemical agents, alterations in environmental conditions or other means to prevent or retard biological or physical deterioration of ocular tissues.

Primary Graft Failure. Corneal edema present from the time of keratoplasty that does not clear after eight weeks and in which there is no known operative or postoperative complication or underlying recipient condition that would explain the biologic dysfunction.

Processing. Any activity performed on the eye tissue, other than recovery, donor screening, donor testing, storage, labeling, packaging, or distribution, such as: testing for microorganisms; preparation, sterilization, steps to inactivate or remove adventitious agents; preservation for storage; manipulation/sizing and removal from storage. Any manipulation of the ocular tissue intended for transplant that involves opening a previously sealed container after recovery.

Processing Establishment. The entity that performs post-recovery tissue processing.

Quarantine. The identification of ocular tissue as not currently eligible for transplantation, including ocular tissue that has not yet been characterized as being eligible for transplantation. Quarantine includes the storage of such tissue in an area clearly identified for such use, or other procedures, such as automated designation, to prevent the premature release of such ocular tissue for transplantation.

Recipient. An individual who receives an ocular tissue transplant.

Recover(y). The removal, acquisition, recovery, or collection of donor tissue.

Recovery Establishment. Entity that recovers tissue from a donor.

Sclera. Fibrous white outer part of the eye remaining after excision of the corneoscleral disc and removal of intraocular content and extraneous surface tissue.

Short term preservation. Eye tissue preservation techniques that maintain viability and/or ultrastructure for less than 5 days. Examples are whole eyes preserved in a moist chamber at 2- 8°C and MK medium.

Source Establishment (or Facility). The entity that releases tissue following donor eligibility determination, and is responsible for maintaining donor records and evaluating adverse reaction reports

Store or Storage. The maintenance of ocular tissue for future use.

Storage Establishment. The entity that stores tissue at any time prior to distribution to the end user.

Storage Solution. Specifies the solution in which the tissue is stored.

Tissue. A functional group of ocular cells, such as cornea, sclera. Tissues may be transplanted as viable cells or otherwise preserved or fixed. Tissue does not include perfusable organs for transplantation.

Tissue Bank. An entity that provides or engages in one or more services involving tissue from living or deceased individuals for transplantation, research, and/or educational purposes. These services include but are not limited to assessing donor suitability (including screening), recovery, processing, evaluation, testing, quarantine, labeling, storage, distribution, tracking, disposition, and recall of tissue.

Tissue Evaluation. Use of microscopy to determine suitability of tissue for surgical use.

Transplantation. The transfer of tissue to a recipient.

Transport Medium. Any microbiological medium capable of maintaining cellular viability during the transport of ocular tissue.

Reportable Items in the Excel Template (in template reporting order)

General

Name of Association. The name of the eye bank association to which the reporting eye bank or country belongs. The Association is responsible for reporting to GAEBA.

Country. The name of the country for which the excel sheet corresponds.

The 'totals' for each country are obtained by the association collating (tallying) the results from all eye bank members in that country.

Initial Data Set Definitions

Number of Corneas Transplanted. The total number of corneas transplanted into one or more recipients. One whole eye may produce only one cornea to count. *Note: At this stage we are not subdividing types of corneal cuts. All transplants of all types are to be tallied into this one total count.*

Number of eligible domestic transplant donors. Total number of humans who have donated ocular tissue that was recovered and intended for transplant.

Number of Corneas Exported To. Total number of corneas reported as exported from one country to another.

Number of Corneas Imported From. Total number of corneas reported as imported from another country into another.

Notes regarding Export and Import. This part of the reporting requires specific origin and destination information collection, i.e. if Australia received 10 corneas from New Zealand, the Australian reporting sheet needs to place a '10' next to New Zealand as their import section. Conversely, on the New Zealand report, we would expect to see '10 exports to Australia'.

Add-On Data Set Definitions

Number of Corneas Recovered for Transplant. Total number of corneas recovered that are intended for transplant.

Number of Adverse Reactions. Total number of recorded events in which a corneal transplant or scleral transplant resulted in the recipient suffering an adverse reaction. Note:

- Graft failure is not an adverse reaction unless the graft failure is due to the introduction of disease to the recipient from the donor or contaminated donor tissue.
- We are not defining the 'adverse reaction' at this stage. We are only collecting the total number of all adverse reactions.

Number of Whole Eye Recoveries. Total number of whole eyes recovered by enucleation.

Number of Cornea-Only Recoveries. Total number of corneas recovered by in-situ excision.

Cornea Storage Solutions Used. A list of storage solutions used to preserve corneal tissue for transplant use.

Number of Penetrating Keratoplasties. Total number of corneas used for penetrating keratoplasties (PK, LAK, femtosecond laser assisted PK, tectonic, and all variations of full thickness corneal grafts).

Number of Descemet's Stripping Endothelial Keratoplasties. Total number of corneas used for Descemet's stripping endothelial keratoplasties (DSEK and all variations, not including DMEK).

Number of Descemet's Membrane Endothelial Keratoplasties. Total number of corneas used Descemet's membrane endothelial keratoplasties (DMEK and all similar variations, not including DSEK) - not the number of segmentations made from one cornea.

Number of Anterior Lamellar Keratoplasties. Total number of corneas used for anterior lamellar keratoplasties (ALK, DALK, partial thickness LKP, and all variations) - not the number of segmentations made from one cornea.

Number of Keratolimbal Allografts. Total number of corneas used for keratolimbal allografts (KLA, KLAL, and all variations of ocular/limbal stem cell transplants, not including amniotic membrane grafts).

Number of Amniotic Membrane Grafts. Total number of surgeries performed in which the eye bank provided ocular tissue or amnion for a surgery involving amniotic membrane grafting (all variations).

Number of Other Keratoplasties. Total number of corneas used for keratoplasties not fitting the description of anterior lamellar, endothelial, posterior lamellar, full-thickness, ocular stem-cell, or amniotic grafting.

Number of Sclera Transplanted. The total number of scleral grafts transplanted into one or more recipients. One whole eye may produce multiple scleral grafts to count. We are therefore counting the number of transplanted pieces – not the number of eyes donated.

Number of tissues processed by the eye bank: This relates to pre-cutting techniques, capturing how many were processed by the eye bank.

Number of injectable corneas: How many pre-cut tissues were pre-placed into injectable devices by the eye bank as a pre-loader.

Tissue for Research: How many consented tissues were provided for ethics approved research

Tissue waste: How many corneas, intended for transplantation were either: discarded due to damage, expiration or utilized for training and research instead.

For Assistance, please contact:

Heather Machin heather.machin@unimelb.edu.au Development and Administration Lead, or Brian Phillippy brianp@lionseyebank.org Data Set and Collector Lead.