Summary of Significant Changes
Section 3.2.1.2 Criteria for ‘urgent’ classification e.g. overwhelming infection

Policy
This policy has been created by the Ocular Tissue Advisory Group on behalf of NHSBT.

The policy has been considered and approved by the Transplant Policy Review Committee (TPRC), who act on behalf of the NHSBT Board, and who will be responsible for annual review of the guidance herein.

Last updated: June 2015
Approved by TPRC: June 2015

The aim of this document is to provide a policy for the selection of adult and paediatric patients on to the UK national transplant list and, where necessary, criteria for their de-selection. These criteria apply to all proposed recipients of organs from deceased donors.

In the interests of equity and justice all centres should work to the same selection criteria.

Non-compliance to these guidelines will be handled directly by NHSBT, in accordance with the Non Compliance with Selection and Allocation Policies

It is acknowledged that these guidelines will require regular review and refreshment. Where they do not cover specific individual cases, mechanisms are in place for selection of exceptional cases (see section 3).

1. Conditions that are considered for transplantation
Conditions that are treatable by corneal transplantation are those in which the procedure can lead to:

- Restoration of corneal structure or function
- Restoration of the integrity of the eye
- Removal of diseased tissue that would otherwise lead to further damage to the eye or body

Corneal transplantation is undertaken where other treatments are unavailable or inferior to corneal transplantation, in order to replace abnormal, defective or abnormally functioning corneal tissue. The indications for corneal transplantation therefore, include:

- Restoration of vision
- Support of the anterior portion of the eye
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- Restoration of the integrity of the globe
- Pain relief
- Excision of tissue for diagnosis
- Removal of infectious or noxious agent
- Replacement of opacified, abnormal or absent corneal tissue to allow visualisation of intraocular structures for, or during intraocular surgery

Those patients in whom there is more than one purpose served by corneal transplantation are categorised according to the primary indication for transplantation, as determined by their treating ophthalmologist.

There is currently no national list for corneal transplantation; each centre holds its own list locally.

2. Assessment of patients
Patients require assessment by an ophthalmologist to determine whether they meet the criteria for corneal transplantation.

The examination of the patient by an ophthalmologist will include at least the following:
- Measurement of visual acuity and visual function
- Slit lamp biomicroscopic examination of the ocular surface, and anterior and posterior components of the eye
- Ancillary clinical tests such as measurement of intraocular pressure

Additional tests and investigations will be determined by the clinical scenario. These may include:
- Corneal topography
- Ultrasound examination of the eye
- Electrodiagnostic tests of visual function
- Confocal microscopy
- Ocular coherence tomography

3. Selection criteria

3.1 Rationale for choice of selection criteria
Corneal transplantation has been shown to be beneficial for the treatment of the conditions categorised in section 1 above.

3.2 Clinical criteria for selection
3.2.1 Criteria for selection

At least one of the following criteria needs to be demonstrated in order for the patient to be eligible for corneal transplantation:
- Vision will be maintained or improved by corneal transplantation
- The eye or integrity of the globe will be maintained or restored by corneal transplantation
- Corneal transplantation will lead to an improvement in the condition
- That the conditions as categorised in section 1 will respond to corneal transplantation
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3.2.1.1 Rationale for ‘urgent’ classification

Patients may be classed as ‘urgent’ to enable allocation of transplant material for conditions in which delay in transplantation will permanently threaten vision or the integrity of the eye.

3.2.1.2 Criteria for ‘urgent’ classification

Corneas may be requested for clinically urgent transplants only for those conditions in which the integrity of the eye will be lost without corneal transplantation. These include:

- Impending perforation (presence of a descemetocoele)
- Actual perforation
- Loss of corneal tissue leading to exposure of the intraocular contents
- Uncontrolled disease that would lead to loss of the eye or unrecoverable loss of vision without corneal transplantation (e.g. overwhelming infection)

3.2.1.3 Other classifications (e.g. sensitised)

In patients with a high risk of allograft rejection due to prior sensitisation, selection for transplantation will first be made according to the anticipated benefit to visual function of a surviving corneal transplant. There is currently no overriding substantial evidence to support the use of HLA matching in corneal transplantation. Ophthalmologists of patients with such conditions may wish to recommend or themselves may wish to be recommended to centres undertaking research involving HLA-matched tissue.

3.2.2 Process for selection of exceptional cases

Where a patient does not meet the criteria listed, or who has a condition for which there is uncertainty regarding the role of corneal transplantation, the clinician (ophthalmologist) should seek advice from the Ocular Tissue Advisory Group (OTAG) through their appropriate regional representative.

3.3 Contraindications

3.3.1 Absolute contraindications

Corneal transplantation would be contraindicated where it will not lead to either:

- Restoration of corneal function
- Restoration of corneal integrity
- Removal of diseased tissue that would otherwise lead to further damage to the eye

Corneal transplantation will be contraindicated in an eye that has no perception of light and is not painful or would not respond to other treatments for pain relief, or in an eye which is ptREPHICAL and will not recover function.

3.3.2 Relative contraindications

Corneal transplantation may be contraindicated when:

- It is likely that it will not achieve the intended outcome
- The conditions causing abnormalities of the cornea and ocular surface will prevent survival of the transplanted cornea or will impede restoration of corneal function and or corneal integrity
3.3.3 De-selection criteria
Patients may be removed from the list for corneal transplantation where their clinical status no longer fulfils the conditions listed under section 3.2.

3.4 Selection for re-transplant
Patients may be selected for repeat corneal transplantation/re-transplant, where they meet the then current criteria listed for corneal transplantation. There is no specified limit on the number of corneal transplants that a patient may have.

4. Appeals process
Patients assessed as unsuitable for corneal transplantation or in whom transplantation is considered a relative contraindication, should have the opportunity for their case to be reviewed by an independent ophthalmologist who is a corneal specialist. A formal process for this is in development.

5. Follow-up on list
Patients should be monitored by their ophthalmologist according to their clinical status, to determine whether their clinical status has changed. This should occur prior to transplantation or in those circumstances where transplantation is contraindicated.

6. Audit
NHSBT conducts regular audits on organ allocation and outcomes.

The outcome of a corneal transplant (graft survival and visual outcome) will be assessed at 1, 2 and 5 years.