POLICY POL189/3

Cornea Transplantation: Allocation

This Policy replaces
POL 189/2

Copy Number

Effective 25/09/17

Summary of Significant Changes

Addition of 30 year maximum differential in age matching criteria between donors and recipients

Policy

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

Last updated: September 2017

The aim of this document is to provide a policy for the allocation and acceptance of organs to adult and paediatric recipients on the UK national transplant list. 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 allocation criteria.

Non-compliance to these guidelines will be handled directly by NHSBT, in accordance with the Non-Compliance with Selection and Allocation Policies http://www.odt.nhs.uk/transplantation/tools-policies-and-guidance/#noncompliance

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 the allocation of organs in exceptional cases.

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1. Allocation policy

1.1 Rationale for allocation policy

In order to achieve equity of access to corneas for transplantation both in terms of time and quality of tissue, the Ocular Tissue Advisory Group (OTAG) will advise NHS Blood and Transplant (NHSBT) on the minimum criteria for the issuing of corneas and on the allocation priority for particular types of transplant.

1.2 How allocation policy was developed

There are more than 150 centres undertaking corneal transplantation in the UK. It has been estimated that approximately 4500 corneas are needed each year (OTAG minutes 3-2-2010). At the time of writing in 2017, approximately 4000 corneal transplants are undertaken each year. There is no national corneal transplant list. The current allocation and distribution mechanism through NHSBT Tissue & Eye Services was developed to improve equity of access of patients to corneas for transplantation through their respective transplant surgeons and to enable the planning of operating lists.

1.3 Allocation policy

1.3.1 Details of policy

Corneas for transplantation must be procured, tested, preserved, stored and distributed by eye banks that are inspected and licensed by the Human Tissue Authority.

There is currently no national transplant list for corneal transplantation; each centre holds its own list locally. Requests for corneal tissue are made by or on behalf of the treating Ophthalmologist to Tissue & Eye Services, NHSBT.

1.3.1.1 Non-priority corneal transplants

The vast majority of transplants carried out are non-priority. In an attempt to allocate corneas fairly to patients waiting for routine, non-priority corneal transplants, OTAG developed a system of corneal allocation on a first come first served basis. In this system, surgeons may request any number of corneas for transplantation but are only allocated more than one cornea if all the primary requests have been fulfilled for that day. Additional requests will then be met providing there are sufficient corneas for allocation.

Corneas that have been issued for a transplant that is then cancelled may be made available for clinically urgent transplants (see 1.3.1.4) or for another patient who can be brought in to hospital at short notice. In both instances, the cornea must be transplanted before the expiry date set by the eye bank.

1.3.1.2 Paediatric corneal transplants

Paediatric recipients are defined as less than 8 years of age. Because of the risk of amblyopia in this age group, paediatric patients are considered to be a priority over routine corneal transplants.

Paediatric patients requiring corneal transplantation are registered with Tissue & Eye Services, NHSBT. Corneas are then allocated to the paediatric patients according to the date when they were registered with NHSBT.

1.3.1.3 Age Matching (30 years maximum differential)

Concern was expressed at the Ocular Tissue Transplant Standards Group¹ regarding extreme age differentials between donors and recipients, particularly in the paediatric age group. Whilst an informal arrangement is in place for age matching, a formal maximum upper age differential of 30 years was proposed and approved by OTAG².

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1.3.1.4 Pre-cut posterior lamellar corneal transplants

Tissue & Eye Services, as of 1st July 2015, now offers pre-cut posterior lamellar corneal transplants for patients with corneal endothelial failure (Fuchs Endothelial Dystrophy, pseudo-phakic / aphakic bullous keratopathy or previous failed keratoplasty) undergoing Descemet's Stripping And Automated Endothelial Keratoplasty (DSAEK). Supplied tissue will have a cap diameter of 9.0 – 9.5 mm, residual corneal thickness of 100 microns with a minimal endothelial cell density of 2,200 cells / mm². Subsequently the service will be expanded to provide pre-prepared tissue for Descemet Membrane Endothelial Keratoplasty (DMEK).

1.3.1.5 Corneal transplants intended for Deep Anterior Lamellar Keratoplasty (DALK)

Donor corneal transplant material intended for DALK will not exceed the age of 80 years of age (Reference: Donor tissue selection for anterior lamellar keratoplasty. Borderie VM et al, Cornea 2013 Aug; 32 (8): 1105-9).

1.3.1.6 Donor and recipient matched corneal transplants

There is currently no overriding evidence for the matching of donors to recipients by either HLA or age. There is a lack of robust evidence to justify the use of donor-recipient matching for HLA antigens to reduce the risk of corneal allograft rejection. Cross-matching has also been shown to be of little or no benefit in corneal transplantation. Matching will not, therefore, be a consideration in corneal allocation. This will be kept under review and revised accordingly in light of any new evidence from appropriately designed outcome studies published in peer-reviewed journals.

1.3.1.7 Urgent transplants

Clinically urgent corneal transplants are defined in the selection policy (http://www.odt.nhs.uk/transplantation/tools-policies-and-guidance/policies-and-guidance/#cornea). Corneas are allocated only to patients who meet the criteria for urgent transplants (3.2.1.2). The surgeon will request corneal tissue from Tissue & Eye Services, NHSBT for an urgent transplant, and in most instances, a cornea will be prepared by the eye bank for use at short notice. These corneas will not be issued according to the standard protocol and the results of the final microbiological tests on the storage medium may not have been completed. Alternatively, a cornea that has been previously issued for a transplant that is then cancelled may be available (see 1.3.1.1).

2. Acceptance of offered corneas

Only corneas that meet the minimum criteria agreed by OTAG are allocated for patients. As such, corneal transplant surgeons are expected to accept all offered corneas without setting additional criteria unless approved by OTAG. There may be quality issues identified as a 'serious adverse event', in which case a surgeon would not use the tissue for the intended purpose. An example of a serious adverse event would be when the cornea that has been issued is found to be damaged or cloudy. Serious adverse events and reactions are reported to the regulatory authority, currently the Human Tissue Authority. The surgeon would put in a further request to Tissue & Eye Services, NHSBT for corneal tissue, which would then be allocated before requests for other non-priority cases are met.

References:

¹ The Royal College of Ophthalmologists: Minutes of the Ocular Tissue Transplant Standards Group meeting held 16th November 2016. (Minute 6a and 6b)

² NHSBT Ocular Tissue Advisory Group: Minutes of the Ocular Tissue Advisory Group meeting held 25th January 2017. (Minute 6.1)

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