Changes in this version

Substantial changes to Policy, please review entire document.

Policy

NHSBT Divergent Outcomes Policy – Response to Signals Arising from Audit of Corneal Transplantation Outcomes

Prepared in consultation with, and supported by, the Royal College of Ophthalmologists

Contents

1. Purpose of paper

1.1. The aim of this paper is to outline the response when underperformance is suspected or divergent outcomes for corneal transplantation have been indicated by NHSBT. The paper describes the methods used to identify potential surgeon outliers, as well as detailing the subsequent actions following a signal of divergence including, where necessary, suggesting further clinical or analytical support.

2. Background

2.1. NHSBT is responsible for ensuring appropriate monitoring of transplantation outcomes in the UK, in this case for corneal transplantation.

2.2. A number of organisations and individuals share responsibility for ensuring optimum and uniform outcomes after transplantation. Stakeholders include patients, donors, transplant health care professionals, employing Hospital Trusts / Boards, Commissioners, Regulators and National Departments of Health.

2.3. In NHSBT, Statistics and Clinical Research are responsible for monitoring transplant outcomes using data supplied by centres/surgeons to the UK transplant registry. Relevant data are collected on the 'Ocular Tissue Outcome and Transplant Record Form', as well as additional follow-up forms at one, two and five years. The quality of data depends on the accuracy of the information provided and level of compliance in returning forms.

2.4. Monitoring allows identification of those surgeons with above average outcomes and so encourages sharing of best practice. If monitoring suggests that outcomes may be less than satisfactory (i.e. a signal is generated), there needs to be a process in place, to ensure the validity of results, and to rectify any potential causes.

2.5. It should be stressed that a signal is merely a trigger for investigation to determine whether there is a cause for concern or not and does not necessarily indicate poor outcomes. The signal must be set at an appropriate level so as not to cause undue concern.

2.6. The aim is not to waste time and resource, or to have an adverse impact on the confidence of stakeholders by potentially increasing risk-averse behaviour. However, it is important to identify sub-optimal practice, thus enabling NHSBT, and others, to offer support, mentoring, and training as appropriate.

3. Identification of potential outliers

3.1. On an annual basis, the Statistics and Clinical Research department produces a confidential report on corneal transplantation for active surgeons in the UK. Each report is surgeon-specific analysing two-year transplant outcomes compared against national rates for keratoconus (KC), Fuchs endothelial dystrophy (FED) and pseudophakic bullous keratopathy (PBK). These three corneal disorders are the commonest indication for corneal transplantation, accounting for approximately 60% of corneal transplants in the UK.

3.2. Three months prior to the circulation of the annual surgeon reports, datasets are produced for surgeons to review their own data, specifically reflecting the time period analysed in the transplant outcomes for KC, FED and PBK. Outstanding transplant and follow-up forms are also notified to improve the data collection and accuracy of the analysis.

3.3. The analysis is performed on data over a 6-year time period for first grafts including contralateral first grafts for each of these indications. For the purposes of monitoring outcomes, KC and FED are considered in the analysis since these indications for transplantation are relatively

straightforward, while PBK and re-grafts are associated with poorer outcomes and possible confounding clinical features. The analysis also takes into account known patient risk factors. For KC, the relevant factors include the patient's pre-operative visual acuity and the presence of ocular surface disease, including inflammation and infection. For FED, the factors considered are the patient's pre-operative visual acuity and the presence of glaucoma.

3.4. Methodology for identifying surgeons that trigger a signal:

- The national graft survival rate at two years post-transplant is estimated using Kaplan-Meier methods and the 95% and 99.8% confidence limits surrounding the national rate are calculated using the score method for the binomial distribution. The score method is appropriate in this case because some surgeons only perform a small number of transplants[1].
- Surgeon graft survival rates at two years are risk-adjusted using a Cox regression model that accounts for patient risk factors commonly associated with graft failure for each indication. For each surgeon, the observed to expected failure ratio is then multiplied by the national failure rate. The resulting value is subtracted from 100%, providing the risk-adjusted graft survival rate. These individual surgeon rates are compared with the national rate using a funnel plot.
- The Department of Health HQIP (Health Quality Improvement Partnership) recommends that an 'Alert' is generated if outcomes fall outside the 95% lower confidence limit of the national rate, and an 'Alarm' if outside the 99.8%[2] lower confidence limit, an approach adopted by the National Ophthalmic Database in the audit of cataract surgery[3].
- Surgeon graft survival rates generating an 'Alert' signal (below the 95% confidence limit) are monitored but not escalated. If a given surgeon wants to explore these findings, we recommend requesting analytical support from Statistics and Clinical Research department or, for clinical support, contacting the Ocular Tissue Advisory Group (OTAG).
- Graft survival rates at the 'Alarm' level (below the lower 99.8% confidence limit) are considered to have generated a signal for concern and warrant further investigation/escalation, as outlined below.

3.5. Please note surgeons performing fewer than 15 transplants for a given indication are not included in the divergent outcome policy due to the large amount of uncertainty surrounding their estimated graft survival rates.

4. Response to a signal

4.1. In response to a signal, the Statistics and Clinical Research department will inform:

- Medical Director (MD) for Organ and Tissue Donation and Transplantation (OTDT)
- Assistant Director of Statistics and Clinical Research / Head of OTDT Studies
- Chair of the Ocular Tissue Advisory Group (OTAG), or nominated deputy if there is a conflict of interest
- Chair of the OTAG Patient Safety and Governance Sub-Committee

[1] Hopkinson C, Curnow E, Larkin DFP, Prydal J, Tuft S. Graphical comparison of surgeon outcomes for the audit of a national corneal transplant registry (OTAG study 32). *Eye* 2023;37:1236-41.
[2] Detection and management of outliers. Health Quality Improvement Partnership. January 2011.
[3] National Ophthalmic Database Audit: Outlier Policy. Royal College of Ophthalmologists. National Ophthalmic Database. March 2020.

4.2. The Chair of OTAG and Chair of OTAG Patient Safety and Governance Sub-Committee will be responsible for ensuring that all interested parties are kept informed as necessary, and where relevant.

4.3. In response to a signal, the ocular statistical lead on behalf of the Chair of OTAG and OTAG Patient Safety and Governance Sub-Committee will send to the surgeon, a surgeon investigations report that includes:

- A letter informing the surgeon that their results have generated a signal.
- The risk-adjusted funnel plot that has triggered a signal.
- A request that the surgeon reviews their datasets to check for any data discrepancies, identifies any additional grafts with risk factors that may not have been reported on the Ocular Tissue Outcome and Transplant Audit form and provide details for transplants with unknown transplant outcomes. This may include transplants for which a new procedure or technique was implemented.
- The surgeon's form return rates is also provided. A lack of follow-up for this time period will be highlighted and may require additional follow-up form submissions.
- A request for a response from the surgeon within 2 months.

5. Outcomes

5.1. Unsatisfactory response

In the absence of a response, or in the case of a non-reflective one, the Chair of OTAG and Chair of ACR will at:

- 1 month: send an informal reminder/advice
- 2 months: send a formal letter to the surgeon re-iterating the request for further analysis and including a copy of this policy
- 3 months: the Medical Director of OTDT sends a letter to the Medical Director of the relevant Trust (copied to the lead clinician for ophthalmology and appropriate commissioners) with a copy of this policy.

5.2. No cause for concern

After reviewing the information sent to the surgeon and their response, if it is agreed by the MD of OTDT, Chair of OTAG, and Chair of OTAG Patient Safety and Governance Sub-Committee that the signal does not represent any underlying cause for concern, the possible cause for a signal or a lack of concern will be documented. The surgeon will be informed of this decision.

5.3. Cause for concern

After reviewing the information sent to the surgeon and their response, if it is agreed by the MD of OTDT, Chair of OTAG and Chair of OTAG Patient Safety and Governance Sub-Committee that the signal does indicate cause for concern, the Medical Director of the relevant Trust (and lead clinician for ophthalmology and appropriate commissioners) will be informed:

- That a signal has been generated
- That a review has confirmed that there is cause for concern
- Suggesting that a support package is drawn up, offering clinical training and guidance from OTAG and OTAG Patient Safety and Governance Sub-Committee
- Documenting dates for repeat audit review.

5.4. Ongoing concern

If despite the actions detailed in the preceding section, there is ongoing concern, the MD of OTDT, Chair of OTAG and Chair of OTAG Patient Safety and Governance Sub-Committee will be responsible for ensuring that all concerns are addressed with the Medical Director of the relevant trust and appropriate commissioners which may require a formal visit.

6. Further work

6.1. Low volume surgeons

Analysis of results by surgeons performing less than 15 transplants for a 6-year time period for each indication presents problems in generating meaningful statistical comparisons. Notably, earlier work has shown that at least for penetrating keratoplasty, results in this group are not necessarily worse than those of high-volume surgeons[4]. Similar studies have not been done for endothelial keratoplasty although there is clear evidence in endothelial keratoplasty of an association of low volume with surgeon learning effects[5]. The concern that graft survival is reduced in this group, but excluded from the analysis discussed here, is acknowledged and work to resolve the issue is under way. This may include investigation of outcomes in the group as a whole, amalgamating patients undergoing similar procedures, or increasing the time frame over which results are analysed.

6.2. Computerised data return and data validity

Computerisation of data collection is under investigation by NHSBT, but unfortunately it is unlikely to be implemented in the near future. While there may be inaccuracies in data returned to NHSBT, the spreadsheet of results sent out 3-4 months prior to the funnel plot analysis provides an opportunity for surgeons to check the validity of data and inform Statistics and Clinical Research of any corrections.

[4] Larkin DFP, Mumford LL, Jones MNA. Centre-specific variation in corneal transplant outcomes in the United Kingdom. Transplantation 2011;91:354-359.

[5] Shanmugaranjan S, Hopkinson CL, Downward L, Larkin DFP. Influence of surgeon learning on outcomes in new ophthalmic procedures: quantified nationwide evidence in endothelial corneal transplantation. *Br J Ophthalmology* 2024;0:1-7