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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 figures 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 for each of these indications because they are considered relatively straightforward whereas re-grafts are known to have poorer outcomes. In addition, grafts with known risk factors are also excluded from the

analysis; for KC, these are the presence of inflammation, infection or ocular surface disease and for FED and PBK, the presence of glaucoma. Thus, outcomes are risk-stratified to a certain degree, enabling a fair comparison between surgeons.

3.4. Methodology for identifying surgeons that trigger a signal:

- Surgeon and national graft survival rates at two years post-transplant are 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. 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%[1] lower confidence limit, an approach adopted by the National Ophthalmic Database in the audit of cataract surgery[2].
- 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 Audit and Research sub-committee of 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 10 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 ODT Studies
- Chair of the Ocular Tissue Advisory Group (OTAG), or nominated deputy if there is a conflict of interest
- Chair of the Audit and Clinical Research Sub-committee of OTAG (ACR) or nominated deputy if there is a conflict of interest.

4.2. The Chair of OTAG and Chair of ACR 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 Chair of ACR will send to the surgeon, a surgeon investigations report that includes:

- A letter informing the surgeon that their results have generated a signal.
- The funnel plot that has triggered a signal with the exclusion of grafts with risk factors

[1] Detection and management of outliers. Health Quality Improvement Partnership. January 2011.

[2] National Ophthalmic Database Audit: Outlier Policy. Royal College of Ophthalmologists. National Ophthalmic Database. March 2020.

- 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 identified on the Ocular Tissue Outcome and Transplant Audit form and that may be excluded in subsequent analyses. This may include transplants for which a new procedure or technique was implemented.
- The surgeon's form return rates. A lack of follow-up provided for this time period will be highlighted and may require additional follow-up form submissions
- An offer of support from the Statistics and Clinical Research department in any further analyses.
- 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: send a letter to the Medical Director of the relevant Trust (copied to the lead clinician for ophthalmology) 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 ACR 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 ACR that the signal does indicate cause for concern, the Medical Director of the relevant Trust (and lead clinician for ophthalmology) 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 ACR
- Documenting dates for repeat audit review.

5.5. 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 ACR will be responsible for ensuring that all relevant interested parties are informed.

6. Further work

6.1. Risk adjustment

Currently, the analysis is restricted to first grafts in each of the major indications with the exclusion of high-risk cases. This approach allows for a certain degree of risk stratification but assumes each surgeon has the same patient case mix. The integration of risk-adjustment as

informed by appropriate modelling, would account for additional factors that may influence graft survival, such as graft type, and other significant patient/transplant factors. One benefit is that graft survival rates would be adjusted for surgeon case mix without the need to exclude certain patients from such analyses and would be more comprehensive.

The plan is to introduce risk-adjusted funnel plots to the surgeon annual reports later in 2021. While the current method should avoid any disincentive to operate on high risk patients, the incorporation of risk adjusted models will give additional reassurance that the audit process is robust and will not have an impact on patient care, and that surgeons will be not be penalised unfairly.

6.2. Low volume surgeons

Analysis of results by surgeons performing less than 10 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[3]. However, similar studies have not been done for endothelial keratoplasty. 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.

6.3. Training

In future models, graft survival rate by the consultant may be separated from those by trainees. However, it should be noted that the overall outcome remains important, consultants being responsible for results of their trainees.

6.4. 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.

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