NHS BLOOD AND TRANSPLANT

OCULAR TISSUE ADVISORY GROUP

CHANGES TO THE NHSBT DIVERGENT OUTCOMES POLICY

BACKGROUND

1 The NHSBT Divergent Outcomes Policy was initially introduced in July 2021, following the release of the latest Annual Surgeon reports. These reports began using a funnel plot to compare surgical transplant outcomes against national graft survival rates.

2 The policy addresses the response to signals that suggest potential underperformance or divergent outcomes in corneal transplantation for keratoconus, Fuchs' dystrophy and pseudophakic bullous keratopathy patients.

3 Since its introduction, minor revisions have been suggested to the OTAG Research Sub-Committee, with the proposed updates outlined throughout the document. The complete draft of the revised policy is attached (POL308 draft update.doc).

KEYS CHANGES TO THE POLICY

4 Surgeons will no longer be monitored for outcomes in pseudophakic bullous keratopathy patients, as this is a higher-risk indication with a smaller number of cases each year. Transplants performed for keratoconus and Fuchs' dystrophy patients will continue to be monitored.

5 A risk-adjusted Cox regression model was generally preferred over the Kaplan-Meier method, as it allowed for a more accurate assessment of surgeon performance by adjusting for significant patient characteristics. This approach was chosen over the previous method of excluding cases with known risk factors. The plan was to implement this method into the Annual Surgeon reports and subsequent NHSBT Divergent Outcomes policy following the identification of these standard patient risk factors (**Appendix**). This approach was initially agreed upon with the Royal College of Ophthalmologists.

6 Low volume poses a risk to the accuracy of the analyses. To increase the cohort size, contralateral first grafts were included in the analysis and factored into these risk-adjusted models.

7 A minimum of 15 transplants will be required in the policy for each indication to address concerns about unnecessarily identifying surgeons due to a small number of procedures. Alternative methods are being explored to identify divergent surgeons with low volume.

8 There was a concern of potentially penalising trainee surgeons, so the suggestion was to exclude all transplants performed by a surgeon within the first year of practising a new technique.

ACTION

9 Members of the group are requested to review the proposed changes to the NHSBT Divergent Outcomes Policy and to assess whether they are satisfied with the clinical risk factors outlined in the **Appendix**.

Cathy Hopkinson **August 2024**

Statistics and Clinical Research

APPENDIX

A.1 Risk factors and categories proposed in the keratoconus risk adjusted rates	
Factor	**Level**
Two-year graft rejection-free model[1]	
Eye grafted	Initial eye
	Contralateral eye
Recipient ethnicity	White
	Asian
	Black
	Other
Recipient age	10-year increase in age
Recipient sex	Male
	Female
Vascularisation	No
	Yes
Two-year graft survival model	
Eye grafted	Initial eye
	Contralateral eye
Pre-operative visual acuity	>6/18
	60/60 – 6/18
	Worse than 6/60
Ocular Surface disease inc. infection and inflammation	No
	Yes
[1] This model will not be monitored in the NHSBT divergent outcomes policy; however, this model will be applied in the Annual Surgeon reports	

A.2 Risk factors and categories proposed in the Fuchs' dystrophy risk adjusted rates	
Factor	**Level**
Two-year graft rejection-free model[1]	
Eye grafted	Initial eye
	Contralateral eye
Recipient ethnicity	White
	Other
Pre-operative visual acuity	>6/18
	60/60 – 6/18
	Worse than 6/60
Recipient age	10-year increase in age
Two-year graft survival model	
Eye grafted	Initial eye
	Contralateral eye
Pre-operative visual acuity	>6/18
	60/60 – 6/18
	Worse than 6/60
Presence of glaucoma	No
	Yes
[1] This model will not be monitored in the NHSBT divergent outcomes policy; however, this model will be applied in the Annual Surgeon reports	

A.3 Risk factors and categories proposed in the pseudophakic bullous keratopathy risk adjusted rates	
Factor	**Level**
Two-year graft rejection-free model[1]	
Eye grafted	Initial eye
	Contralateral eye
Recipient age	10-year increase
Presence of glaucoma	No
	Yes
Pre-operative visual acuity	>6/18
	60/60 – 6/18
	Worse than 6/60
Recipient ethnicity	White
	Asian
	Black
	Other
Two-year graft survival model[1]	
Eye grafted	Initial eye
	Contralateral eye
Presence of glaucoma	No
	Yes
Recipient ethnicity	White
	Asian
	Black
	Other
Pre-operative visual acuity	>6/18
	60/60 – 6/18
	Worse than 6/60
Recipient age	10-year increase
[1] This model will not be monitored in the NHSBT divergent outcomes policy; however, this model will be applied in the Annual Surgeon reports	