NHS Blood and Transplant

To be ratified OTAG(M)(23)02

NHS BLOOD AND TRANSPLANT
ORGAN AND TISSUE DONATION AND TRANSPLANTATION DIRECTORATE
OCULAR TISSUE ADVISORY GROUP (OTAG)
ON WEDNESDAY 13 SEPTEMBER 2023
AT WILLIAM HARVEY ROOM, NHSBT FILTON, BRISTOL
MINUTES

Present:

Name of attendee	Initials	Place of work / Centre represented
Parwez Hossain	PH	**Chair, OTAG**; Assoc Prof Ophthalmology, Southampton
Kyle Bennett	KB	Assistant Director Tissue and Eye Services (Patient Services), NHSBT
Jackie Brander	JB	Head of Service Delivery, OD and Nursing, NHSBT
Fiona Carley	FC	Consultant Ophthalmic Surgeon, Manchester
Jennifer Court	JC	Ophthalmology, Torbay and South Devon
Francisco Figueiredo	FF	Consultant Ophthalmologist, Newcastle Eye Centre
Cathy Hopkinson	CH	Senior Statistician, Statistics and Clinical Research, NHSBT
Nigel Jordan	NJ	Head of Department, East Grinstead Eye Bank, Queen Victoria Hospital
Derek Manas	DMM	Medical Director, OTDT, NHSBT
Nardine Menassa	NM	Consultant Ophthalmic Surgeon, St. Paul's Eye Unit, Liverpool
Lisa Mumford	LM	Head of Statistics and Clinical Research, NHSBT
Steph Norris	SN	NHS Graduate Management Trainee, NHSBT
Michael O'Gallagher	MOG	Specialty Improvement Lead (Cornea) & Medical Information Officer, Belfast
Trushar Patel	TP	Consultant Ophthalmic Surgeon, South Tees Hospitals
Ulrike Paulus	UP	Consultant - Tissue and Eyes, NHSBT
Azizur Rahman	ARa	Moorfields Eye Hospital, London
Amanda Ranson	AR	Head of Operations Tissue and Eye Services (Patient Services), NHSBT
Dalia Said	DS	Consultant Ophthalmic Surgeon, Nottingham
Konstantina Soumilas	KS	Statistician, Statistics and Clinical Research, NHSBT
Derek Tole	DT	Consultant Ophthalmic Surgeon, Bristol Eye Hospital
Geraint Williams	GW	Consultant Ophthalmic Surgeon, Worcester
Emma Winstanley	EW	Lead Nurse, Tissue and Eye Services, NHSBT
Kevin Wright	KW	Service Development and Performance Analyst, NHSBT

In Attendance:

Olivia Quinn	OQ	Medical Director and Group Support, NHSBT
Caroline Robinson (Minutes)	CR	Advisory Group Support, NHSBT

	ITEM	ACTION
1.	**Introduction, Welcome and Apologies**	
	• PH welcomed all to the meeting. • Apologies were received from A Chandrasekar, A Chung, E Hollick, F Larkin, J Micciche, M Popiela, M Rajan, A Safdar • There were no Declarations of Interest at the meeting. • *Attendees are asked to take note that it is the policy of NHSBT to publish all papers on the website https://www.odt.nhs.uk/*	

	unless the papers include patient identifiable information, preliminary or unconfirmed data, confidential and commercial information or will preclude publication in a peer-reviewed professional journal. Authors of such papers should indicate whether their paper falls into these categories prior to or at the time of the meeting.	
2.	**Minutes of the last meeting (9 November 2022) - OTAG(M)(22)02**	
2.1	Accuracy – The Minutes were accepted as a true record with the following amendment: • The initials and name for M Rajan will be corrected so they are consistent and accurate.	
2.2	Actions – • It was noted that the re-launch of pre-cut DSAEK grafts has taken place following implementation of OCT. • DMM stated that any proposals for research should be presented at the Research and Development group (replacing RINTAG) in line with the work of the other advisory groups. **ACTION: L Marson to be invited to the Audit and Research sub-group meeting on 13 December.**	**P Hossain**
2.3	Matters arising, not separately identified – NAD	
3.	**Medical Director's Report**	
	• DMM outlined the role of the advisory groups following OTAG's inclusion. There are 10 advisory groups for all solid organs, plus the Retrieval Advisory Group (RAG), Research and Development and the National Organ Donation Committee (NODC). They aim to advise on policy and to enable best practice and clinical advice and to instigate changes to allocation, offering and other new initiatives. • Organ Utilisation implementation and the ongoing workstream is key work currently for OTDT. • Finances are very tight across the board without confirmed sustainable funding in many areas. • The Eye Summit, held earlier in the summer, was very successful and all at this OTAG meeting are encouraged to sign up to and implement the recommendations. • There are no new appointments to report at present.	
4.	**Eye Summit recommendations and report**	
4.1	Minutes from the Eye Summit - **OTAG(M)(23)01** – were circulated prior to the meeting	
4.2	PH gave a presentation of key points from the Eye Summit which is circulated with these Minutes – **OTAG(23)11** - This includes international comparators demonstrating the donor shortage of corneas in the UK compared with other countries despite the UK's large population numbers. Three big wins were highlighted for the Summit: • To improve the efficiency of the eye retrieval pathway with the option to increase ERS. • To improve utilisation and quality of tissue • To improve equity of access Key priorities for the ophthalmology donation and transplant community to consider now were listed as: • To set up additional ERS - At present, it is not clear what funding is available from NHSE so other options are being	

	explored and a business case will go to the NHSBT Board shortly. • To gather prospective recipients into a registry – this would enable prioritisation by clinical need. • To promote local trust communication on eye donation and improve trust engagement – Level 1 hospitals should be promoting eye donation. • To look for ways to reduce delays in the eye donation process. • To promote greater SNOD involvement in eye donation – this may require a working group – Currently, individuals are not currently being approached for eye donation despite many donors being on the register for both organ and eye donation. • To encourage eye donation by more work with local hospices – it is possible that end of life services are not aware of the possibilities for eye donation. However, the need for appropriate training to approach families regarding donation was emphasised. • To enhance the efficiency of the pathway by conducting research and innovation in eye donation, eye banking, and tissue viability. The need for having guidance for setting up systems in regions was emphasised. It was noted that despite attempts to engage with large hospital trusts, there has been very little improvement in donations, and it has been hard to get NHSE to set targets within contractual arrangements. There is also a lot of work underway with local hospices and a contract with the Scottish National Blood Transfusion Service covering all Scotland. Work is ongoing on what works well.	
5.	**Current Allocation Process / Proposal to change the Group Status**	
	Patients are currently allocated as follows: • Group 1 is for emergency/urgent patients. • Anyone allocated in Groups 1 and 2 is allocated a cornea and are booked into hospital as soon as possible (1 week for Group 1; 6-8 weeks for Group 2) • There are insufficient NHSBT corneas to meet the demand for Group 3 and Group 4 patients. Corneas are allocated to the longest waiters based on data provided by NHSE for the Recording and Reporting Referral to Treatment (RTT) pathway. • If requests are received from Scotland and N. Ireland, these are inserted into the list. • NHSBT also imports excess corneas from Venice (usually 2 per month and 60 in August when they don't operate) and negotiations are ongoing to add a tissue bank in Spain to the import licence. Previously there have been discussions with tissue banks in the USA and work is ongoing with these regarding meeting European retrieval standards. This allocation process works well for hospitals who have managed their lists well, but if there are now Group 3 and 4 patients who are not long waiters, they will not be allocated corneas. If hospitals are importing from overseas, they will not be allocated NHSBT corneas to ensure that patients across the country have equitable access to treatment. There are sufficient donor numbers and processing facilities in the UK to be self-sufficient.	**P Hossain**

	Some minor modifications between Group 1 and Group 2 were suggested: • Group 1 – Emergency - proposed to split as <24 hours or <72 hours - <24 hours would be perforation required corneal transplant and <72 hours at risk of imminent perforation and/or therapeutic (infection) or emergency RD surgery likely. • Group 2 – Urgent - blind binocular 3/60 with transplant likely to restore vision to better than 3/60 and/or enable fundus new needed for acute treatment. • Group 3 -Semi-urgent - pain, binocular VA <6/18 (partially sighted) where transplant will restore vision to better than 6/18 and/or to relieve pain and/or significantly reduced QoL with inability to work/function due to binocularly reduced vision and/or congenital or acquired corneal opacity that may cause amblyopia. • Group 4 – Routine – binocular VA <6/12 and or other clinical need and/or keratoprosthesis (KPro). NHSBT will not change how it allocates but there would be a change to how patients are listed on the RTT form for Groups 3 and 4. It was agreed that it is often hard to distinguish between Groups 3 and 4 and there can be inconsistency in interpretation of the RTT across different trusts regarding patient activation. It is suggested that NHSE needs to better define what the RTT is for. A working group was suggested to decide on criteria for Groups 3 and 4 and there will be no changes in the meantime to the criteria. **ACTION: PH to form a working group to decide how Groups 3 and 4 can be revised.**	
6.	**NHSBT Operational Update**	

6.1	Data reported on referrals, deferrals and retrieval pathway - **OTAG(23)05** – This presentation by KW (Service and Performance Analyst with responsibility for data collection at OTDT) was circulated prior to the meeting.
	• Referral pathways into NRC are through.
	  ○ Specialist Family Approach (SFA) – these are usually cold calls from hospitals,
	  ○ Eye Retrieval Schemes (ERS)
	  ○ SNODs
	  ○ Traditional (TRAD) – ie, the family calls to donate eyes
	  ○ Unsuitable for Organs (UOR)
	• There are 30 deferral reasons from which only one can be selected per referral.
	• About 50% of potential donors do not die in hospitals post COVID.
	The data from these pathways is shown in the presentation. There are not necessarily SNODs on all sites and dedicated Tissue Co-ordinators could aid the process.
	• It was noted that there is often insufficient information recorded and this is a legacy from the separate directorates of organ and tissues historically and offers opportunity going forward.
	• There are also complexities around the systems DonorPath and TissuePath and NHSBT continues to receive multiple different referral forms, some with inconsistent information resulting in delays in assessing donation suitability.
		K Bennett

	• Regarding COVID as a deferral reason, there are mixed views about whether this is now valid. At present, the policy states that there can be no donation from COVID positive donors despite a lack of data indicating transmission risk. **ACTION: KB to bring this issue up at the next JPAC meeting regarding acceptance criteria.**	
6.2	NRC – EW gave an update on the ongoing work with the University of Southampton to look at the potential of donation from hospices and care settings. Discussions are taking place with healthcare professionals, families and patients about how to facilitate donation who have expressed a need for more education. • Phase 1 - Five organisations (mainly hospices) are involved in the study (which started on 25 August) to test ideas and educational packages. Work is also ongoing with Hospice UK over 4-6 months to gather more data to decide the best way forward. • Phase 2 – work is taking place with palliative care units in hospitals and care homes. There is limited funding for the pilot and then a further case will need development for further funds. Operationally the NRC is fully staffed. All the referrals coming in are reviewed and matrons are going out to all teams.	
6.3	Eye Retrieval Schemes – no further discussion	
6.4	Retrieval and Eye Banks - **OTAG(23)02** – There are still 3rd party retrievers for certain sites that can't be accessed and this is under constant review. • Work is ongoing with the Scottish Transfusion service to develop a strategy for tissue and eye donation in Scotland going forward and further information will follow at future meetings. • There is capacity within the Eye Banks in Bristol and Liverpool to increase activity. There is approval for DSAEK prepared corneas, but DMEK corneas are not being implemented currently due to stipulations from the HTA that this should be provided with full thickness to allow surgeons to prepare their own separation. However, stock levels mean that sending two corneas out for one transplant does not seem appropriate. This will be reviewed when stock levels increase. **ACTION: KB to look at HTA restrictions again** • Contamination rates – from January to end August this is 2.6% in Bristol and 1.71% in Liverpool. Contamination in Dextran pre-transplant is 0.06% in Bristol and 0% in Liverpool. Post transplant is 0.23% in Bristol and 0.08% in Liverpool. All these rates are considered positive outcomes.	**K Bennett**
7.	**Clinical Governance Group Report – OTAG(23)10**	
	UP gave a summary which is circulated to all members. • There was a spike in adverse trends in 2019 in relation to problems encountered with pre-cutting when the service was transferred. This has been resolved with the introduction of OCT imaging of pre-cut grafts and the trend is now relatively stable. • This trend is similar for graft failures. However, an audit is ongoing to understand primary graft failure definitions. • The number of failure reports that go into the registry are probably 3 times as many as we receive, but this may be in	

	situations where the surgeon knows the graft has failed due to surgical issues rather than a specific graft problem. • The annual Cornea Activity report indicates an increasing demand for DMEK - an increase in 30% in the last 2 years. Some surgeons are concerned whether this is due to diabetes. Surgeons are reminded that grafts from diabetic donors are not a deferral reason, although some literature indicates that donor diabetes can make graft preparation more difficult. • Surgeons are reminded that issued grafts are only suitable to the request. Swapping grafts in hospital for different types of transplant may lead to a graft being unsuitable. • Cornea grafts do not automatically fulfil donor eligibility criteria for use of the scleral rim or consent for R&D. • Chlorhexidine rinse has been introduced in NHSBT Eye Banks.	
8.	**Statistics and Clinical Research reports**	
8.1	<u>Corneal donation and transplantation activity</u> – **OTAG(23)04** – In this report circulated prior to the meeting, long term outcomes were analysed over the last 20 years for corneas retrieved to NHSBT and corneas transplanted in the UK. Short-term outcomes were broken down by quarter over the last five and half years. Summary statistics were used to compare activity over time. • There was a decrease in cornea donation due to COVID-19, although this has recovered by 4% in the last financial year. There's also been improvement in the last quarter. • Transplant activity is an under-estimate due to a lack of reporting the tissue outcome and transplant record forms. This is a mandatory service requirement and surgeons are reminded of the importance of form completion. • Deceased solid organ donors were impacted by COVID-19 but to a lesser extent than cornea-only donors, deceased solid organ donors are younger and die in specific circumstances such as in ICU.	
8.2	<u>Suitability of corneas for transplantation</u> – **OTAG(23)06 -** The purpose of this paper circulated prior to the meeting was to monitor the outcome and suitability of corneas donated to NHSBT Eye Banks (see attachment).	
8.3	<u>Corneas issued and not used for transplantation</u> **- OTAG(23)08 -** This paper explores the reasons why corneas were discarded at the transplanting centre and investigates a lack of reporting from some centres. • Most corneas issued by NHSBT are transplanted however there's been a large increase in the number of corneas issued that are recorded with an unknown outcome; 444 (12%) in 2022/23. • In the last year, 119 (3%) corneas were confirmed as discarded by the transplanting centre compared with 168 (5%) in 2012/13. The main reason corneas were discarded was reported as 'other' (N=59, 50%), followed by 'recipient reasons' (N=25, 21%) in 2022/23. • An additional 'unused tissue reason' codes provided on the back of the Tissue Outcome and Transplant Record form **FRMTISSUEOUTCOME v8.0 – DRAFT (circulated as OTAG(23)09 below** •	

8.4	FRM Tissue Outcome form - **OTAG(23)09 -** This form was updated to provide clearer instructions, and improvements were made to the layout of the front page. It is hoped this will capture more detail about why corneas are being discarded at the transplanting centre and improve form return rates. There is currently no funding for online submission of forms. This form was approved by the group. **ACTION: CH to implement the new form**	
8.5	Statistics and Clinical Research update - **OTAG(23)07 –** This was circulated for information.	
9.	**OTAG Audit and Research subgroup - OTAG(23)03**	
	In F Larkin's absence, PH reported that a meeting of the Audit and Research group was held on 28 June and Minutes were circulated to OTAG members. • J Prydal has now stepped down from the group and M Rajan has agreed to join. OTAG members are asked to consider joining the group as one further surgeon is needed. **ACTION: Interested candidates to join the group to contact F Larkin.** • Work undertaken by the group are itemised in the Minutes circulated and further work is described in the Statistics and Clinical Research update paper • The next meeting will be on 13 December.	**ALL**
10.	**Serum Eye Drops / Amniotic membrane update**	
	KB reported that the process for ordering and issuing eye drops is being streamlined as the target was not being reached. • At one point 230 patients were waiting for treatment. • The new process put in place has reduced this number to <80. The delay in getting treatments out to patients meant there was a reduction in patients being referred. Now that the backlog is being reduced the referrals are again increasing. A Chandrasekar will be contacting consultants to find out whether patients still need eye drops and this will help determine whether the waiting list is accurate. There has also been an increase in the number of requests for amnion so a piece of work is underway to determine whether an increase or analysis of membrane donations is needed and how this can be improved to meet requests. In Scotland only allogeneic transplants are done (not autologous)	
11.	**Any other business**	
11.1	Membership of OTAG – PH reminded members that if they are unable to attend a meeting it is helpful to send a representative. The membership of OTAG is currently being checked to ensure there is representation for all the UK.	
11.2	Date of next meeting – The next meeting will take place at the end of February – Further information to follow	