NHS BLOOD AND TRANSPLANT
ORGAN AND TISSUE DONATION AND TRANSPLANTATION

THE MINUTES OF THE FORTY FIFTH MEETING OF THE OCULAR TISSUE ADVISORY GROUP AT 10:00 AM ON 10th OCTOBER 2024 THE WESLEY HOTEL AND CONFERENCE VENUE

ATTENDEES:

Parwez Hossain (PH)	OTAG Chair, South Central Representative
Derek Manas (DM)	OTDT Medical Director
Azizur Rahman (AR)	Chief Biomedical Scientist, Moorfields Eye Hospital
Richard Baker (RB)	National Lead for Governance, NHSBT
Kyle Bennett (KB)	NHSBT Assistant Director Tissue and Eye Services
Jackie Brander (JB)	NHSBT Head of Operations - Donations, Tissue and Eye Services
Fiona Carley (FC)	Liverpool Eye Bank Representative, North West Representative
Akila Chandrasekar (AK)	Transfusion Medicine Consultant, NHSBT
Jennifer Court (JC)	Southwest Representative
David Essex (DE)	Moorfields Eye Bank Representative
Cathy Hopkinson (CH)	NHSBT Senior Statistician
Mark Jones (MJ)	NHSBT Statistician
Nigel Jordan (NJ)	East Grinstead Eye Bank Representative
Michael O'Gallagher (MO)	Northern Ireland Representative
Elisabeth Partridge (EP)	NHSBT Tissue Donation Nurse Specialist
Ulrike Paulus (UP)	OTAG Governance Group Chair, NHSBT
Steven Potter (SP)	Lay Member
Madhavan Rajan (MR)	East Anglia Representative
Amanda Ranson (AR)	NHSBT Head of Operations, Tissue and Eye Services
Dalia Said (DS)	East Midlands Representative
Konstantina Soumilas (KS)	NHSBT Statistician
Nicola Symes (NS)	NHS England Commissioning Representative
Martin Watson (MW)	Moorfields Representative
Geraint Williams (GW)	West Midlands Representative
Kevin Wright (KW)	NHSBT Service Development and Performance Analyst

IN ATTENDANCE:

Chloe Bainbridge	Clinical & Support Services, NHSBT

APOLOGIES: Derek Tole, Filton Eye Bank Representative

1. Declarations of Interest

No conflict of interest was declared at the meeting.

2. Minutes of the OTAG Meeting held on 28 February 2024

2.1 The minutes were confirmed as accurate.

2.2 Action Points

AP1 – Ongoing: KB will clarify approval for the DMEK roll-out with HTA and centres. There have been delays due to COVID-19. Retraining of staff has commenced. 50 DMEK cut corneas were required for HTA approval. Currently, 40 are processed at NHSBT. **KB**

AP2 – A historical Terms of Reference could not be found; therefore, a new ToR will be written up and brought to the next OTAG meeting to align tissues and organ meetings. **KB**

AP3 – The Research and Development Group need volunteers. This may result in a steering group outside of OTAG to discuss items that will need to go through OTAG. **ALL**

2.3 Matters arising, not separately identified

None raised.

3. Medical Director's Report

DM reminded the group that in alignment w, it with all other advisory groups. This meeting is where decisions are made that lead to changes in practice. While other meetings occur outside of advisory groups, any policies requiring modifications must go through OTAG.

RINTAG was disestablished, and now ROFG, co-his aired by G Pettigrew and E Lawson.

Environmental Sustainability group has been established. DM invited the group for expressions of interest in their involvement.

There is a lot of transformation in progress at NHSBT that hasn't yet been refunded by NHS England.

Transformation programme updates:

Sustainability and Certainty in Organ Retrieval (SCORE) – DM gave the group an update on the SCORE project and its aim to improve the sustainability of organ retrieval by tackling issues maintaining the workforce required to sustain retrieval.

Assessment and Recovery Centres (ARC) - organs are retrieved and perfused on machines to improve utilisation.

Donor characterisation – improvement of communication of donor infections and malignancies.

Intensive Care Units

Access to ICUs has changed post-pandemic, with fewer beds available and staff availability to perform brain stem testing, leading to missed opportunities for donations.

Governance

An overview of the CUSUM process in organ groups was given, and an acknowledgement was given that this is not the method used in governance

for corneas. There needs to be more involvement with governance for corneas and SAEARs reporting for full NHSBT oversight so that NHSBT can provide support and help to improve service and/or identify systemic issues that NHSBT can help fix. DM, therefore, suggested that the governance process be looked at to enable this model of governance support in the same way as organs.

Organ Utilisation Groups
All the transplant centres are working together so patients can move from one transplant centre to another for organ transplantation. DM raised that this would be good to consider for patients awaiting corneal transplants while acknowledging this process would be complicated.

4. Statistics and Clinical Research Reports

4.1 Corneal donation and transplantation activity

Presented by KS. Refer to OTAG(24)07 for information.

KB and NS confirmed that 4000 people have been waiting over a year for a Transplant in England alone.

For those not familiar with the consent for donation process, JB offered the group examples of the process of consent for corneal donation from a SNOD perspective while making clear that SNODs approach on all occasions for corneal donations:

1. DCD donors - SNODs follow up on those patients to allow corneal donation. The follow-up can occur over a number of weeks while the NRC makes at least 2 calls per day with ICUs for patient updates.

2. 'Unsuitable for organs' patients - There are patients who are referred to SNODs as potential organ donors and quickly identified during the referral process as unsuitable for organ donation. Due to how the system is currently set up, further conversations with the NRC may not occur. As a result, there is presently a pilot going on from the start of October in North West and Yorkshire donation regions whereby, on all occasions, SNODs would be taking full, detailed assessments of patients and directly handing them over to the NRC. It was stressed that, at this point, not all these potential donors are deceased. This pilot is being reviewed over 1 month.

RB queried how 700 potential donors who undergo characterisation but do not have organs used are managed. JB confirmed that where consent for corneal donation has been provided, donors will have corneas retrieved unless there are contraindications for corneal donation.

4.2 Corneas issued and forms not returned
Presented by MJ. Refer to OTAG(24)08 for information.
NS stated that hospitals are being commissioned to provide a service so NS can work with hospitals to ensure that contracted services include the return

of yellow audit forms as part of a mandatory audit of clinical outcomes from transplant surgery.

DM confirmed that medical directors of hospitals used to be written to highlight such governance issues suc,h as organ transplant audit return form rates and corneal transplants are no exception and need to align with organ governance issues are
DE raised that it would be beneficial for an electronic process to complete yellow form audit outcomes, especially where there is a lack of personnel to perform a time-consuming process for surgeons and hospital staff.

MO offered that the audit data may be provided from a spreadsheet in the interim until there is a better solution to an electronic submission system. CH added that this may work on an ad hoc basis, but principally, the data is affected by the backlog of the forms and updates required.

NS offered to link data with NHSBT in the future. An issue with audit forms returned where imported corneal t sue was utilised. NHSE will have been charged centrally for the costs of such imported tissue. Therefore, providers are required to send audit data and yellow forms as NHSE has paid for this activity per service level agreements with trusts.

NS and MJ

Action: Arrange further discussion of steps to enable the sharing of data of trusts that use imported tissue to cover gaps in data, resulting in insufficient information from centres using corneas.

4.3 Changes to the NHSBT divergent outcomes policy
Refer to OTAG(24)09 for information.

The group agreed to proceed with the method proposed per point 4 of the paper presented.

4.4 Corneal donation and transplantation equity
Refer to OTAG(24)10 for information.

Following the presentation, NJ reported that Retrievals occur, but there aren't many NHSBT retrievals. Eye banks offer to retrieve that they are happy to go out to, but they don't get asked to perform the retrievals.

KB clarified that it has not been due to the consent rate or ability to retrieve; it's more the number of referrals, particularly in the larger hospitals that don't have referral systems in place and reinforced that NHSBT isn't turning retrievals down due to capacity, that it is the lack of referrals coming in.

NS has stated that NHSE has agreed to funding for 2024/2025 to improve retrievals.

DS queried whether the retrieval training could be implemented so that local consultants could perform eye retrievals. KB stated that in the past, individuals have been cleared/trained to retrieve on NHSBT's behalf. However, there were a number of safety issues which prompted a review of

the retrievals. This highlighted that some individuals only performed retrievals around 4 times a year, which meant there was difficulty in maintaining training and competency for enucleation, labelling blood samples, paperwork, and all other critical parts of the process.

There are a number of third-party eye retrievers still in use in the arts of the country, which NHSBT will have difficulty accessing, and there is also high demand. The number of third-party retrievers is intentionally much lower than it used to be, but it does not mean this area can be re-visited.

DM supported that this would not be impossible to do, but they must be trained, accredited, have the appropriate credentials, and be re-evaluated frequently. KB stated this is now performed with third-party retrievers, but the number is much lower.

KB stated that there is a need for more referrals to come in first.

5. Allocation and Selection Policy Review

Refer to OTAG(24)11 for information. ***Post-Meeting Note** The paper circulated did not reflect the current policy. This is to be shared post-meeting.*

KB explained that P1 and P2 patients are prioritised when NHSBT receives requests for corneas. P3 and P4 patients are then reviewed for the position on the waiting list to receive the remaining corneas. The protocol works well for P1 and P2 patients but greatly disadvantages P3 and P4 patients who face a prolonged period on the waiting list.

AC raised that this has been a long-standing issue and that there wouldn't be a need for categories if there wasn’t a supply shortage. Therefore, this highlights the need to increase eye donation rates. Someone will always be more urgent than a P3 or P4, but other nuances are not shown in the current system, such as the degree of sight loss of P3 and P4 patients awaiting corneas.

KB shared that NHSBT gets a weekly update of the waiting list from NHSE. NHSBT will review the leftover demand and availability, after which the remaining cohorts can be moved further along in the allocation process. There is no set time for this, as it depends on demand and availability.

NS referred to the eye donation rates where there are not enough corneas to meet supply and the occurrence of patients in routine categories not receiving corneas for a prolonged period due to being a routine patient as there are always patients that are "super-urgent".

MR added allocation should not be based on waiting time but on the degree of vision loss. However, NS stated that within the NHS Directives, there is a need to reduce the waiting times.
NS suggested that corneal tissue not being a matched tissue currently falls within the rules of the NHS, that it is like other treatments and not seen in the same way as organs that are matched tissues.

P Hossain

Action: Investigate how corneas can be categorised to meet the criteria for being allocated per clinical need rather than waiting time in the form of a working group (involving operational, clinical and governance).

Trusts were not publishing waiting list times previously, though this has changed. NHS England are, therefore, aware of the situation regarding cornea allocation and selection inequity. A prioritisation system was proposed around the start of the pandemic and requires revision for implementation.

Action: Establish a working group for further discussion involving commissioners for a new criterion for fairer allocation of corneas to all patients. **P Hossain**

6. Local arrangements for consent from the next of kin for eye donation

JB provided an update on the pilot, stating that NHSBT can access local electronic systems to enable consent. It has been piloted with Newcastle. The consent would be undertaken under NHSBT's HTA licence for consent.

The process is standardised as the process is currently being performed by NHSBT. However, there is a quality and data security concern for the local nurses having access to NHSBT systems that are being considered, particularly concerning third-party access to the donor register, which poses a high risk for inappropriate access to data. There are potential licencing issues with HTA compliance with regulations if not perceived as a priority for local centres.

7. NHSBT Operational Update

7.1 Data reported on referrals, deferrals, and retrieval pathway

KW and EP presented the performance of the OTDT Referral Pathways/Ocular Donation (also covers items 7.4 and 7.5).

The presentation covered the referral routes through NHSBT: notification of death and contact to family, unsuitable for organ donation and eye retrieval schemes (existing schemes).

JB added that for SNOD referral, there is a caveat to the pilot (*discussed as agenda item 7.2*) that it is not fully understood what the true potential is at the point of referral due to SNODs using DonorPath which is not connecting with other systems therefore not all the information is taken which would give a better idea of the potential for referral for corneal donation.

One of the members reported anecdotally that there won't be calls made for retrieval unless it is known if retrievers are available or if there is access to the mortuary.

There may be retrievals that have to occur out of hours and can only be funded by the Trusts. KB reminded the group that NHSBT retrieval capacity is 7 days a week.

There was discussion surrounding retrieval capacity impacting the consenting rates as Specialist Nurses are uncomfortable discussing donation with families in cases where there is no capacity for retrieval and fear of letting families down. KB and JB stressed that the Specialist Nurses should seek consent for corneal donation at every consent conversation under the assumption that there is capacity for retrieval rather than asking if there is retrieval before approaching families for consent and subsequent referral. If the referral is made and it is later determined that retrieval cannot occur, this can be re-visited. At the moment, there is capacity, and more referrals are needed. If issues are identified, NHSBT can deal with them.

JB stressed that the process may be uncomfortable in the approach, consent, and referral for a short period, which may not end in a retrieval; however, this is the only way to resource corneas. There has been support from Antony Clarkson (Director of Organ and Tissue Donation and Transplantation that SNODs need to be making the approach. There cannot be assumptions made about the capacity to retrieve.

7.2 Project Lead iOrbIT Update

JB has provided an update that NHSBT is engaged with 9 different sites, and one site has gone live. It has taken longer than expected, but progress has been made despite the complexities.

The first site to go live was the University Hospitals of North Staffs (Stoke-on-Trent), which went live in October. Site' go-lives' will be very staggered from hereon.

Time has been taken for engagement with NHSBT, and referral patterns have been looked at to get a systematic review of where the focus needs to be made in the scheme. JB thanked everyone for their patience in the progress.

Recap the aims of the project to improve approach, consent and retrieval.

Eventually, we will have a scheme that can supply 8000 corneas, so there will not be a need to import corneas. However, it's key to note that this improved number is expected to increase over time.

All schemes are expected to go live by the end of March 2025. NHS England is informed monthly on the progress of the scheme. It is hoped that there will be a significant improvement in the number of corneas by December 2025.

PH queried what would occur if the project did not meet the intended achievements; JB and KB are constantly reviewing the progress as it's also important there isn't a scenario where there are too many corneas imported and retrieved, leading to discarded corneas.

A recruitment process is underway to appoint retrieval staff.

7.3 Existing Eye Donation Schemes Update

7.3.1 **Newcastle Consent Pilot Update**

JB provided an update on the pilot, stating that NHSBT can

access local electronic systems to enable consent. It has been piloted with Newcastle. The consent would be undertaken under NHSBT's HTA licence for consent.

The process is standardised as the process is currently being performed by NHSBT. However, there is a quality and data security concern of the local nurses having access to NHSBT systems that is being considered, particularly concerning third-party access to the donor register, which poses a high risk for inappropriate access to data.

There are potential licencing issues with HTA compliance with regulations if not perceived as a priority for local centres.

7.4 **BAU Referral Pathways Update**
See agenda item 7.1

7.5 **Hospice Update**
KW and EP provided a presentation on the performance of the OTDT Referral Pathways/Ocular Donation.

Data from the pilot site has been available for over a year. There has been considerable learning from the pilot site to translate into future work.

All sites are educated to assess patient criteria. Only eligible patients are approached for corneal donations. This has led to good quality referrals in the pilot so far.

Looking forward to the next phase, which includes working with more sites. There has been some time getting these up and running (8 provisional sites to come on board with the programme). It is hoped there will be more data to present to the group in the future.

7.6 **Retrieval and Eye Banks**
AR provided an update.

The cornea wastage among retrieval teams is being examined. Since 1st January 2024, there has been an increased number of short notice cancellations from hospitals (day of cornea receipt) – 108 time expired because they've arrived at the hospital and are no longer needed. Hospitals are not informing NHSBT of cancellations, which may include patients being sick and surgeons being sick.

There are staff who can reallocate corneas at short notice. However, these 108 corneas include those wasted where there has been no time to reallocate the cornea at short notice (within 24 hours).

MR has pre-op appointments close to the procedure date so that anything that may indicate the procedure cannot go ahead is identified early on so that rearrangements can be made. It is unknown how long different centres leave check ins with patients before the procedure.

7.7 **Update on importation of corneal tissue**

AR provided an update concerning a supplier audit performed for Barcelona and Venice Eye Bank.

A due diligence paper exercise was performed for both establishments where no issues were identified; therefore, the HTA approved imported tissues. However, when both eye banks were subjected to site visits and inspection, there were some findings where both eye banks do not meet HTA requirements.

While they meet the requirements of the EU Directive, they do not meet how the HTA have interpreted the EU Directives. This has led to issues with the HTA, which we are working through.
For the 40 corneas imported over the summer of 2024, there has been a special dispensation to provide the corneas under agreement with the HTA. However, TES cannot import further tissue from these eye banks until the findings have been fully addressed and resolved.

KB explained that this did not necessarily mean the imported tissues were unsafe, but they did not comply with HTA regulations as required.

PH requested the scale of importation so that the impact is known; however, it was addressed earlier in the meeting that NHSBT does not know all the data on imported tissue due to missing return of forms for patient outcomes from hospitals.

Action: Provide an update on the Barcelona and Venice Eye Banks. **K Bennett/A Ranson**

8. Clinical Governance Group Report

UP provided updates:

- There is potential for undertaking online SAEARS reporting to see if this is workable regarding resources (IT support, Information Governance).

- UP would like to encourage surgeons who report to NHSBT issues that are actual hospital issues as opposed to actual SAEARs: The yellow transplant outcome form is a good place to report this as "tissue issued but not used" with a range of reasons to choose from, so that the information given can be logged as a hospital reason and not a tissue reason.

- NHSBT is conducting an audit of medical deferrals to examine the detail for anything that can be learned from these deferrals.

- It is important to make a particular graft request when required. For different types of cornea grafts, the tissue is matched to the type of grafts. It cannot be assumed that a graft will always be suitable for any type of procedure; Tissue and Eye Services need sufficient information as part of the request procedure to undertake suitable graft allocation. Grafts may not be suitable for a different procedure from what they have been allocated for. Concerning this, there is work underway looking at ways to modify the graft-

related paperwork slightly to enable input of comments and sharing more on the suitability of the graft incl. sclera suitability.

- **Eye donor ages (Paediatric Eye Donors)** have been discussed with regard to the lower-end

age limit. Colleagues of OTDT have raised whether there is a need to go lower than the recommended 3-year age limit. Following input from paediatric surgeons, there is a reluctance to go lower than 3 years of age. However, a project may be put together to provide evidence of the outcomes of grafts from younger donors outside of the UK.

The DS(A)EK pre-cut service has undergone a couple of audit periods and has now been fully implemented with OCT imaging of all pre-cut grafts. One of the audit outcomes was to monitor SAEARs related to pre-cut corneas. There are very few SAEARs, and U Paulus was happy to report that the service seems stable. There may be work in the future to harness data to fine-tune the release specifications.

- There have been several SAEARs this year where

dissatisfaction was communicated regarding the cap being detached from the pre-cut graft. UP would
like to encourage users to use these grafts as this is not considered an issue with the safety and quality of the graft. This has been discussed with the Medical Eye Bank Directors, who have confirmed- that this is not an issue.

- There are fortnightly calls with Medical Directors & PH

where SAEARs and enquiries relating to the suitability of specific grafts currently in the eye banks are discussed, including ocular donor history and how this may or may not impact donor tissue suitability.

PH wished to point out that , surgeons who submit SAEAR reports or have any other questions, comments or concerns are regularly communicated with, and they appreciate the contact to ensure the situation can be resolved and support can be given. It is uncertain whether grafts directly imported get the same quality reporting and investigation, whereas tissues provided by NHSBT go through thoroughly approved HTA-compliant tissues.

DM indicated that other advisory groups represent different units and queried how these constructive messages for improvements in practices are shared amongst the community. PH indicated that the feedback to the community may rely on the representatives attending OTAG, but how messages are communicated may not be clear. There is a lot of information to process during
a several-hour period of the meeting, and it is important to report on which messages to communicate.

DM advised that the key messages of the meeting are decided at the
meeting in alignment with other advisory groups so that the key messages

are given to the community. PH suggested a regular newsletter should be sent out on behalf of OTAG.

There was an idea for a rotational regional representative to produce a letter where the other regions can agree to the newsletter's content to ensure the summary of critical information can be shared. This would start from when each OTAG minutes becomes available. Each representative that writes the letter will send a draft for PH and DM to approve for accuracy before dissemination.

9. OTAG Audit and Research Subgroup

9.1 PH gave an update on behalf of Frank Larkin, Consultant Surgeon at Moorfields Eye Hospital, who had given his apologies:

1. David Lockington (Glasgow) has joined the group in place of Stephen Tuft (Moorfields).
2. Overseas corneas are being imported where reporting of transplant outcomes are not being sent through, which has led to some concerns. As imported corneas are funded through NHSE, centres should be reporting back. However, there have been many private cases, so there is a question of how these are followed up.

   KB offered the NHSBT position, stating that they would follow up with any patients they were notified of, whether private or not. NHSBT can only follow up patients where they have been given patient details as they can only follow up on what is known. MR suggested this would be an ideal topic to add to the newsletter, particularly concerning regulations and reporting back follow-up information.

   NJ indicated private surgeons are unlikely to provide yellow forms from private providers for follow-up for corneas. NS stated that people they are unaware of are difficult to legislate with compared to those who have private surgery and receive private imports.

   NJ queried if a cornea for an NHS Trust would be getting money from NHSE if they have to source corneas from a private provider for an NHS patient. NS stated that while the communication hasn't yet gone out, NHS Trusts will be invoicing NHSE, and Trusts will be reimbursed for the cost. It was suggested that forms be completed as part of invoicing. This would include a reminder that form return comes under requirements as part of HTA licenced activities.

   Post meeting note F Larkin would like the group to be aware that for the benefit of surgeons and their patients, the audit subgroup is mainly concerned with having information on the scale of this activity and transplant outcomes. OTAG reps, please remind any surgeons in their regions using such corneas to register these grafts and provide follow-up at 12, 24 and 60 months for NHSBT-sourced corneas.

   F Larkin would also like the group to know that the subgroup

welcomes suggestions for corneal transplant projects. Project application forms can be obtained from Cathy Hopkinson c/o NHSBT.

10. Amniotic Membrane Update/Serum Eye Drops

Amniotic Membrane

AR reported issues with amniotic membranes and bio-burden (discard rates at ~75% for bacteriology reasons). There have been a lot of investigations into this. While investigations are in place to understand what led to the need to discard tissue previously, there has also been an increase in donation rates, so tissue numbers are where they should be in terms of numbers. There will be some comms to be shared soon that tissue is ready to order then due to healthy stock numbers. As part of the concurrent investigations, it has not been possible to replicate the same conditions again. The investigations so far have indicated that it is possible that bacteriology was donor-derived as well.

Serum Eyedrops

AC reported that the programme is going from strength to strength. In September 2024, 500 batches were issued to patients, reflecting the level of activity undertaken at NHSBT Tissue and Eye Services. The service is doing everything possible to turn around patient requests as quickly as possible. The biggest challenge has been meeting patient demand when serum eye drops are required.

There is some work to go through changing the patient database to ensure the patient records include those currently and actively requiring treatment. AC said that NHSBT will contact clinicians to check their patients' statuses.

PH queried the reason for the eyedrops being so costly as a treatment. KB clarified that this was due to only one provider of the dispensing system used.

FC reported that there had been great overall feedback from patients, and it has made a huge difference to them. FC also praised the customer care services.

11. Any Other Business

DS reported that European regulations are changing and will be effective in August 2027. They are expected to make an impact, and there is a need to perform gap analyses, which will be extensive work.

Work towards developing In-situ incision is still in progress, and A Ranson will report on the situation at the next OTAG.

Professor Paul Rooney sadly passed away recently.

11.1 Date of next meeting

26th February 2025, on Microsoft Teams (invite to follow).

12. Key points to cascade to team members from this meeting

A newsletter will be published to include the tissue shortage and plans to address the shortage, a revision of patient criteria, and the issue of corneas that are not used, leading to a considerable amount of wastage. MR agreed to write the newsletter. **MR**