

**NHS BLOOD AND TRANSPLANT
ORGAN AND TISSUE DONATION AND TRANSPLANTATION
THE MINUTES OF THE FORTY SIXTH MEETING
OF THE OCULAR TISSUE ADVISORY GROUP (OTAG)
AT 1 PM ON 26 FEBRUARY 2025 - VIA MICROSOFT TEAMS**

ATTENDEES:

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| Parwez Hossain | OTAG Chair, South Central Representative |
| Agrawal Ashish | Representative for Scotland / East Lothian |
| Kyle Bennett | NHSBT Assistant Director, Tissue & Eye Services |
| Fiona Carley | Liverpool Eye Bank Representative, North-West Representative |
| Akila Chandrasekar | Transfusion Medicine Consultant, NHSBT |
| Cathy Hopkinson | NHSBT Statistics and Clinical Research |
| Nigel Jordan | East Grinstead Eye Bank Representative |
| Stephen Kaye | NHS England, National Clinical Lead for Eye Donation |
| Frank Larkin | Consultant Ophthalmic Surgeon, Moorfields Eye Hospital, London |
| Derek Manas | OTDT Medical Director |
| Sundas Maqsood | SE Representative (Consultant - Maidstone and Tunbridge Wells) |
| Michael O'Gallagher | Northern Ireland Representative |
| Elisabeth Partridge | NHSBT Tissue Donation Nurse Specialist |
| Ulrike Paulus | OTAG Governance Group Chair, NHSBT |
| Steven Potter | Lay Member, NHSBT |
| Azizur Rahman | Chief Biomedical Scientist, Moorfields Eye Hospital |
| Amanda Ranson | NHSBT Head of Operations, Tissue and Eye Services |
| John Richardson | Assistant Director, Organ and Tissue Donation, NHSBT |
| Konstantina Soumilas | NHSBT Statistics and Clinical Research |
| Michael Stokes | Head of Hub Operations |
| Nicola Symes | NHS England Commissioning Representative |
| Derek Tole | Consultant Bristol Eye Hospital / Medical Advisor Filton Eye Bank |
| Geraint Williams | West Midlands Representative |
| Emma Winstanley | Lead Nurse, TES Patient Services, NHSBT |
| Kevin Wright | NHSBT Service Development and Performance Analyst. |

IN ATTENDANCE:

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| Caroline Robinson | Advisory Group Support (Minutes) |
| Lawna Pugh | Advisory Group Support (Observer) |

APOLOGIES: Jackie Brander (Head of Operations – Donations, NHSBT), David Essex (Moorfields), Nardine Menassa (Liverpool Rep), Madhavan Rajan (East Anglia Rep), Dalia Said (East Midlands Rep), Martin Watson (Moorfields)

| ITEM | | ACTION |
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| 1. | Welcome and Declarations of Interest | |
| | P Hossain welcomed everyone to the meeting. Apologies are shown above. There were no declarations of interest. | |
| 2. | Minutes and Action Points of the OTAG Meeting held 10 October 2024 | |
| 2.1 | <u>Accuracy</u> – OTAG(M)(24)02 – K Bennett's points have been noted and will be checked with the Chair prior to upload to the OTDT website. | |
| 2.2 | <u>Action Points</u> – OTAG(AP)(24)02 – Circulated but not discussed. | |

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| 2.3 | <u>Matters arising, not separately identified</u> - NAD | |
| 3. | Medical Director's Report | |
| | <p>D Manas gave the following update:</p> <ul style="list-style-type: none"> • <u>Terms of Reference</u> - The ToR for the group is being updated along with ToR for all other advisory groups to ensure consistency. Centres are reminded that they should endeavour to have representation at each meeting. • A new Patient Advisory Group is being developed to ensure each organ/tissue is represented. • <u>Finances</u> – A response from the DH will be shared in due course once the settlement is approved. It is hoped this will enable funding of some transformation work. • <u>Transplant Oversight Group (TOG)</u> – This group has a governance element regarding performance management, quality etc. There are references to TOG in NHSE's contractual arrangements for governance so OTAG's involvement in this group would be welcome. A meeting coming up will confirm this. • <u>Consent</u> – A 2-day face to face event is being planned for June to look at consent issues across all solid organs. The hope is that improved consent rates will also benefit tissue donation. • <u>IT resources</u> – return of yellow forms, details of adverse events and processes remains problematic. Work ongoing on matching and offering and organ allocation schemes will be the first piece of work. • <u>ODR</u> - It is agreed that retrieval of the whole eye will be looked at with the Ethics Group as information is currently misleading to ensure that it is clear to donor families that the whole eye is being donated. There is no capacity to inform those people who are already on the ODR. It is noted that every family is consented before donation takes place and this involves very clear explanation of what takes place. | |
| 4. | Statistics and Clinical Research reports | |
| 4.1 | <u>Corneal donation and transplantation activity</u> – OTAG(25)01 – The aim of this paper, circulated prior to the meeting, is to review short-term and long-term corneal donation and transplantation trends in the UK. Please see paper for details. | |
| 4.2 | <p><u>Outstanding forms not returned</u> – OTAG(25)02 / OTAG(25)04 – The paper circulated explores the reasons why corneas were discarded at the transplanting centre and investigates outstanding form returns. OTAG members are asked to look at how returns of outstanding forms can be improved. The group was also asked to approve a letter to be sent to the Medical Directors of NHS trusts regarding this issue. It was emphasised that return of forms is important to ensure good governance.</p> <ul style="list-style-type: none"> • It was noted that consultants are being approached for forms that are awaiting outcome despite returning all forms. One challenge is that when the cornea is issued with the transplant record form, it might be that a linkage hasn't been made between the donor identification number and the tissue type with the transplant recipient. • The resources and the manual process in place is currently insufficient to manage a large volume of transplants performed across the UK. An electronic portal could help to ensure information is collected in real time. | P HOSSAIN |

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| | <ul style="list-style-type: none"> It was noted that when a digital connection was set up for organ transplants some trusts found it difficult to send forms electronically therefore a digital solution alone may not work. <p>ACTION – As this issue is importance for governance, a working group in OTAG will be set up.</p> | |
| 4.3 | <p><u>Statistics update</u> – OTAG(25)03 – this paper was circulated prior to the meeting. OTAG members are asked to let C Hopkinson know of any additional papers that would be useful.</p> | |
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| 5. | Clinical Governance Group report | |
| | <p>U Paulus gave an update from the Governance meeting that took place on 25 February 2025.</p> <ul style="list-style-type: none"> Fortnightly calls to discuss unexpected eye bank findings and ocular history queries as well as selected SAEAR reports continue with Eye Bank advisors and P Hossain. Meetings also include occasional presentations and updates from guests. The DMEK pilot will soon take off. Clinical criteria for follow up are being discussed as the pilot is assessed. The group also considered occasional requests for splitting tissues and what advice can be given out. Work has been started to put a few criteria together to help people. A minimum donor age has been under discussion following a request by colleagues in OTDT who felt that the minimum donor age could be lowered. However, the minimum donor age of 3 is line with other countries and there is concern that younger donor tissue does not handle as well as tissue from older donors. Work is ongoing on an online SAEAR reporting process. 2024 was a busy year in terms of SAEARs, but there do not appear to be any particular concerning trends or signals. Reports of fibres on grafts were highlighted. The source of these has not been identified, but they have not caused any reported clinical issues. However, they can look very frightening and obviously if surgeons feel uncomfortable using the grafts, that is understandable. Epithelial shedding can give an impression of white spots on the grafts that can resemble infective infiltrates. Some surgeons are comfortable to use the grafts, but it is understood if they are rejected. DMEK graft preparation failures are monitored as some surgeons are concerned about using tissue from diabetic donors. However, the causes of DMEK graft preparation failures are multifactorial and overall the number of failures with concomitant donor diabetes is very low. Demand for DMEK grafts is high and rising whilst there is an overall shortage of grafts. <p>AGREED: a) The governance structure needs to be more formalised as there is current reliance on individuals b) The name of the group will also be changed to reflect the change to Patient Safety elsewhere in NHSBT.</p> | U PAULUS |
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| 6. | NHSBT Operational Update | |
| 6.1 | <p><u>Data reported on referrals, deferrals, and retrieval pathway of all schemes</u> – OTAG(25)05 – Full details are given in the presentation from K Wright was circulated prior to the meeting.</p> <p><u>Referral Pathways into the NRC</u></p> | |

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| | <ul style="list-style-type: none"> • There has been an increase in referrals during Q3, in part due to return to normal levels in the SFA route and two new eye retrieval schemes going live. • Phase 2 of the hospice project has gone live. Hospices were separated out from 21 December when TissuePath went live. Hospices will now be recorded separately to TRADs. • Hospice route has been separated out from TRAD from Dec21. <p><u>Unsuitable for Organs Referral Pathway</u></p> <ul style="list-style-type: none"> • Unsuitable for Organ Referrals pilot has gone live in Yorkshire & North West, expanding into Midlands from Jan 25. • Across the three pilot regions, minimum data sets are completed the SNODs and sent to the NRC. These are reviewed and approached\consented as appropriate by the NRC. • These referrals may have also come in via a different referral route e.g. TRAD. The record within TissuePath is then updated. <p><u>Discards</u></p> <ul style="list-style-type: none"> • There was an increase in discard rates across most teams throughout December. This is thought to be impacted by a reduction in orders over the festive period, and the extra time corneas spent in organ culture media. <p>G Williams also highlighted the work of palliative care colleagues in Herefordshire who had converted from 2020 donors from 28 referrals for a pilot study they were doing. The conversion rate was 71%.</p> | |
| 6.2 | <p><u>Project Lead IORbIT Update</u> – J Richardson stated that the purpose of the I-ORbIT scheme is to increase the number of schemes from 5 existing to 15 in England. The 10 additional schemes are supported with NHSE funding. There is also one more in Cardiff.</p> <ul style="list-style-type: none"> • Two of the schemes are now fully live in Stoke and Salford and these are performing well. Stoke has hit its quarterly target and Salford is on target. There are also 3 additional sites to roll out in Salford. • 2 other schemes are progressing well, and it is hoped to sign contracts with them in March. • Engagement continues with the remaining 6 schemes. • Winter pressures have had a big impact on timelines. However, once schemes have gone through internal governance they are up and running very quickly. NHSBT is ready to do onsite training. • Work is also ongoing to identify where traditional referrals came from previously so that these hospitals can be engaged in new developments and included in training. Each potential pathway needs to be maximised, but this will take time. | |
| 6.3 | <p><u>Existing Eye Donation Schemes update</u> – For the 5 existing schemes:</p> <ul style="list-style-type: none"> • Work is ongoing to make them 7-day services; currently they are 5-day services. • A new potential donor audit has been introduced to ensure there is better data coming from all schemes and they can be benchmarked to draw out any variance in performance. | |
| 6.4 | <p><u>Hospice update</u> – This is going well with high quality referrals. There is an opportunity for more work, but the team has been hit by absence recently.</p> <ul style="list-style-type: none"> • Work is ongoing on how to work with colleagues on end-of-life care and education packages are starting. Phase 1-5 hospices are engaged, and Phase 2 will be 10 hospices. • There are 8 more hospices in Phase 4. | |

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| | <ul style="list-style-type: none"> Community deaths need more consideration. Palliative care says many die in the community. Work is ongoing with 4 hospices on this. 30 hospices are waiting to engage. The impact of educational tools has resulted in an increase in referrals and good feedback. Hospice UK is on board. There will be a presentation at their conference in November. An e-learning package will go live on 31 March. | |
| 6.5 | <p><u>Retrieval and Eye Banks</u> – A Ranson gave an update:</p> <ul style="list-style-type: none"> On the Eye Bank and Retrieval side, HTA inspections took place at Filton and Liverpool sites in January. Both were successful with inspectors on the sites for about 8 days looking at all areas of the pathway from referrals to providing corneas for transplantation. They also visited Information Services where all follow up forms go. Work continues with colleagues in NHSE and the recovery team to reduce waiting times for Groups 3 and 4 patients towards the 65-week target. As of 20 February 2025, there are 364 patients waiting and the plan is to try to reduce the wait to 52 weeks as soon as possible. Meetings take place with NHSE every 2 weeks to review this. Work is also ongoing with NHSE to review 2024 cases where there were cancellations following acceptance. There were 140 occasions in English transplant centres where the operation was cancelled. Of these, 76 were cancelled by the hospital. NHSE has contacted all providers to ensure all corneas retrieved can be placed. Corneas were reallocated where possible at short notice and a list of centres who will accept these at short notice is being compiled. There were 49 occasions where NHSBT had to cancel the surgery, and the highest reason was DSAEK equipment failure. Discard data is being reviewed and a visual library of cases is being compiled for training packages. New material will go out in April. A clinical evaluation of DMEK tissue is planned to begin in March with 5 surgeons and the outcome of this will be shared as soon as it's finished. <p>ACTION: OTAG agreed to celebrate the 40th anniversary of the Bristol Eye Bank by holding the Spring meeting of the group in Filton to coincide as far as possible with the anniversary date. The meeting will include a history of the Eye Bank.</p> | ADVISORY GROUP SUPPORT |
| 6.6 | <p><u>Update of importation of corneal tissue</u> – K Bennett updated as follows:</p> <ul style="list-style-type: none"> Last year several corneas were imported from the Venice Eye Bank as they had an excess during the summer months. On site audits were performed before this took place whereas only desk top audits were possible previously. Some non-conformances were identified in how EU directives are translated into UK law and applied by the HTA. Venice is very established and is regulated by the competent authority in Italy and meets the standards as set out by the Commission, but not how the HTA has interpreted the standards. An audit report was sent back to Venice and the response is the Eye Bank there will implement HTA requirements to ensure they can meet UK standards. None of this means the tissue imported is not safe. A similar exercise took place with corneas from Barcelona who also had an excess. However, Barcelona is not prepared to change their criteria. Although they would have retrieved on NHSBT's behalf, they | |

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| | <p>will not be importing into the UK, and they have sufficient corneas to meet their own needs.</p> <ul style="list-style-type: none"> An EU directive defines how corneas are consented, processed, stored and distributed for transplantation. This is then transposed into Member state law, and this creates issues for importation into the UK. Only Venice and Barcelona have been audited to date. <p>It was noted that it is likely no Eye Bank outside the UK will have the requirements of the HTA in place and that a robust gap analysis and mitigating risks need to be in place. The group advised checking how individual hospital trusts import their tissue and what procedures take place in situ.</p> <p>ACTION: K Bennett to look into this.</p> | |
| 6.7 | <p><u>Costs and Charges for Research and Training</u> – A number of training and research centres have highlighted their concerns about the high costs of resourcing eyes. Previously there was only a carriage charge, but now there are additional costs which results in special budgets being requested from the Deanery. When requests are refused this creates challenges for training as well which is hard for centres to understand, particularly as many of the eyes would otherwise have been discarded for transplantation. The justification for the increase in costs was explained as follows:</p> <ul style="list-style-type: none"> Any tissue diverted from clinical use to research needs to be registered in the repository which has a cost. This is necessary to ensure traceability and order stability. NHSBT operates on a cost recovery basis. Someone is employed to physically store, take orders, send out tissue which is another cost. NHSBT gave 2 years' notice that the charge was coming in to allow time for teams to build it into their costings. <p>ACTION: K Bennett agreed to look at the costs through the research subgroup.</p> | |
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| 7. | Selection Policy Review | |
| | <p>The current regional allocation policy was set in 2017. NHSE now want to review and revise the corneal specification and selection.</p> <ul style="list-style-type: none"> A new subgroup will be formed for this. NHSE has 6 clinicians currently for service specification. P Hossain asked the OTAG group to nominate volunteers to join this group. There are 3 policies within NHSBT, and these will be in draft. <p>ACTION: K Bennett to send to N Symes at NHSE</p> <ul style="list-style-type: none"> Allocation is in the realm of NHSBT although certain wording needs to be the same as in the NHSE document. A separate NHSBT working group is needed to update this. Input to this group is important from the whole UK. Clinical risks can also be included. <p>ACTION: Volunteers to contact P Hossain offering to work on this group.</p> | K BENNETT / ALL |
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| 8. | OTAG Audit and Research subgroup | |
| 8.1 | <p><u>OTAG representative for Research and Development Group – OTAG(25)06</u> – This document was circulated prior to the meeting. The last meeting was held in December.</p> <ul style="list-style-type: none"> F Larkin stated that the group feels that Ocular Tissue should have a voice on NHSBT's Research Committee. <p>ACTION: D Manas and P Hossain to check who the representative is.</p> | D MANAS / P HOSSAIN |

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| | <ul style="list-style-type: none"> • <u>ToR for subgroup</u> – F Larkin has been preparing new ToR for the subgroup. It was noted that a generic form will be provided in due course for use by all the subgroups connected to the advisory groups so that there is a consistent and unified approach. • <u>Low return rate of forms</u> – The subgroup is concerned about this issue and its potential impact on longer term outcome studies. The forms affect a lot of projects and 3 have already been shelved due to unsatisfactory 2 year follow up rates of transplants. The subgroup offered its help to any centre/institution with any resource or other issues there are. It was noted that it will be a mandatory requirement for trusts to provide transplant outcomes for patients and filling in forms will be part of the new NHSE specification. Failure to comply may also have financial implications for trusts. | |
| 9. | Amniotic membrane update / Serum Eye Drops | |
| | <p>A Ranson gave an update:</p> <ul style="list-style-type: none"> • <u>Amniotic membrane</u> - there has been promotional work including TV and other press coverage. Amniotic membrane requests are increasing for different clinical indications and additional amniotic products are being explored. • <u>Waiting list for serum eye drops</u> – There has been an overwhelming number of requests for repeat treatment. Work is ongoing to clear waiting lists. • <u>2 days continuous improvement event</u> – This has been held to help modernise the service. The actions from this will be shared in due course. | |
| 10. | Terms of Reference for OTAG and sub-groups | |
| | <i>See Item 3</i> | |
| 10.1 | <u>Membership and attendance of OTAG -</u> | |
| | OTAG members are reminded that they should try to attend the 2 meetings held per year or send a representative so that all centres and regions are represented. Advisory groups are where decisions are ratified and so it is important to have appropriate representation from the entire group. | |
| 11. | Newsletter – OTAG(25)07 | |
| | <p>This newsletter put together by M Rajan was circulated prior to the meeting. Many comments are probably now superseded by issues discussed at this OTAG meeting, so there will be a revised updated version sent to members shortly.</p> <ul style="list-style-type: none"> • It was noted that it was important to know the sign off date for any items for the newsletter and to make it clear who was responsible for the contents (NHSBT, the OTAG Chair or a particular trust). • Members need to be aware of the deadline and the contents need to be checked to ensure there are no inaccuracies. <p>AGREED: the newsletter should be from OTAG and subgroups should check for any inaccuracies.</p> | M RAJAN / P HOSSAIN |
| 12. | Any Other Business | |
| 12.1 | <u>Date of next meeting</u> – WEDS 25th SEPTEMBER 2025 – Filton, Bristol. Invitation to be circulated to membership in March. | |
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| 13. | Key Points to cascade to team members from this meeting | |
| | <p>The following key points should be circulated to team members following this meeting:</p> <ul style="list-style-type: none"> • Numbers are still short of pre-pandemic figures for transplant although there have been some improvements in eye donation. • A quarter of eye donations are from imported tissue. • Return of forms are low and a working group will be set up to look ways of improving this. • A new OTAG Patient Selection and Allocation Group will be set up and work will be ongoing with NHSE on this. Allocation remains in the realm of NHSBT. • The Clinical Governance group will be re-named as Patient Safety and Governance Group. • There are good levels of amniotic and serum eyedrops being provided. | |