

**NHS BLOOD AND TRANSPLANT
MINUTES OF THE OTAG EYE BANK SUB-GROUP MEETING HELD AT 11.00 A.M.
ON FRIDAY 3 JUNE, STOKE GIFFORD, BRISTOL.**

PRESENT:

John Armitage (Chair)	Bristol Eye Bank, Head of R&D-Ocular, Tissue and Eye Services
Kyle Bennett	Deputizing for Helen Gillan, Tissue and Eye Services
Hazel Bentall	Lay Member
Fiona Carley	Consultant Ophthalmologist, Manchester Eye Bank
Francisco Figueiredo	Consultant Ophthalmologist, Newcastle (Phoning in)
Nigel Jordan	East Grinstead Eye Bank
Khilan Shah	Moorfields Eye Bank
Derek Tole	Consultant Ophthalmic Surgeon, Chair OTAG, Bristol Eye Bank
Paulus Ulrike	Consultant Haematologist, NHSBT

1 Welcome & Apologies

Apologies were received from Emma Hollick, A Chandrasekar, Isaac Zambrano and Chris Bowerman

Ulrike Paulus, Consultant Haematologist, Tissue and Cell Donation and Transplantation, NHSBT, was welcomed as a member of the Eye Bank Subgroup.

No declarations of interest

2 Minutes of the Eye Bank sub-group

2.1 Accuracy

Page 2 – 3.1 – removed the reference to DULK

Page 4 – 6.3 – there are 8 (not 9) schemes

Page 5 – 9.1 – ARVO on a new line with comma then May 2016.

**CSS
(Complete)**

2.2 Action Points

1. Completed
2. A Chandrasekar sent an email stating that this had been discussed in OTAG and then JPAC. She had circulated a change notification with a change to the first sentence: *'corneas should be stored into storage solution no longer than 24 hours post enucleation'*. (NB See minute 4.1 for actual wording in the JPAC Change Notification.) Death to retrieval did not require any change and it is specified in 21.12.1 – Eye Retrieval section; "Enucleation should be carried out as soon as possible, but no longer than 24 hours after death". This was covered on the agenda.
3. Discussion regarding how best to take forward Action Point 3 (regarding appearance of Epithelium) – F Figueiredo and F Carley to discuss.
4. Other incidents/Governance Issues - On agenda
5. Eye Retrieval manual corrections – K Bennett to check with A Ranson that corrections have been made.
6. New services – Eye bank preparation for DMEK – on agenda

**F Figueiredo/
F Carley**

**K Bennett/
A Ranson**

7. Commercial organ culture media and other solutions – KB to update
8. Chlorhexidine trial – complete and on agenda
9. The use of donor corneas after laser refractive surgery for DMEK only. The NRC and Customer Services team need to be made fully aware of this change in donor selection criteria. J Armitage and U Paulus will take this forward as part of the review of Donor Selection Guidelines.
10. Implementation of ISBT 128 – on agenda

**J Armitage/
U Paulus**

2.3 Matters Arising, not separately identified

There were no other matters arising.

3 Governance

3.1 SAREs reported to HTA

J Armitage asked that these should be listed and attached to the minutes as C Bowerman and I Zambrano were not present to give a report. K Bennett reported two SAREs from Bristol Eye Bank regarding primary graft failures (both EK). Unfortunately, the surgeons had not returned the tissue to the eye bank and, in one of the cases, the cornea had been fixed in formalin thus precluding PCR analysis for herpes virus. D Tole reiterated that surgeons should always send the tissue back to the issuing bank for investigation and he would raise this again at OTAG. Prompt reporting of SAREs by surgeons, decisions about whether SAREs are reportable to the HTA and responsibility for investigation and logging actions are the main issues. J Armitage will meet with Nick Weston and C Stevenson (QA, NHSBT Filton) to discuss these points. N Jordan reported two cancelled operations owing to particles shed from the spears used during the pre-cutting of the grafts for DSAEK. N Jordan to feedback to D Tole the manufacturer of the spears for dissemination to surgeons at OTAG and the Chair of the Governance Group.

D Tole

J Armitage

**N Jordan/
D Tole**

3.2 Serious Untoward Incidents (SUI)

K Bennett reported an incident at St Thomas's where a pre-cut DSAEK cornea was supplied even though the surgeon had not requested a pre-cut cornea. The patient had suffered a failed graft and the details, including type of graft, for that previous request automatically populated the new request on NTxD. J Armitage to raise with David Stagg. There was also confusion over the wording used on NTxD to describe the different types of graft that a cornea could be used for. J Armitage would review the wording and circulate to Eye Bank Subgroup members before raising with David Stagg.

J Armitage

3.3 Other incidents

K Shah spoke about a cornea that was to be delivered to Croydon but the courier by mistake delivered the transport box to an insurance company. The error was resolved.

3.4 Governance Structure/Issues

U Paulus raised the subject of internal and external communications and the question of interaction between the NHSBT Governance pathway and the OTAG Governance Subgroup.

- D Tole has reconvened the OTAG Governance Subgroup to provide professional oversight and to look for trends in SAREs reported to and investigated by NHSBT.
- All SAREs should be notified to Mark Batterbury, Chair of the OTAG Governance Subgroup, and U Paulus and a report prepared for OTAG.

D Tole
U Paulus

4 Donor Selection

4.1 Report from SAC-TCTP

A Chandrasekar was not present to give this report and J Armitage had been unable to attend the most recent SAC-TCTP meeting. The JPAC Change Notification No.23-2016 states: 'Corneas should be excised and placed in an appropriate storage solution as soon as possible, but no longer than 24 hours after enucleation. This Change Notification requires one amendment: the second sentence refers to storage for up to 2 weeks at 4°C, which should read 3 weeks. J Armitage to notify A Chandrasekar. Other than that, the document was noted and the requirement for processing to occur within 24 hours of enucleation will be implemented.

J Armitage

Hospitals that import corneas from outside the EU must ensure that they comply with the EU Tissues and Cells Directive and the UK Blood Services standards set out in the 'Red Book'. The importation of corneas requires an HTA licence and must be through an HTA licensed tissue establishment.

4.2 Tissue Donor Selection Guidelines – review

U Paulus had reviewed the guidelines with J Armitage and a summary would be produced. There were some items that needed clarification with ophthalmologists (D Tole, F Carley, D Lake), microbiologists, neuropathologists and other specialists as required. U Paulus also suggested updating the entries on eye disease and eye surgery (e.g. LASIK no longer an absolute contraindication since these corneas may be suitable for DMEK). Approval from OTTSG to be sought before submitting changes to SAC-TCTP.

**U Paulus/
D Tole/
F Carley/
D Lake**

5 Eye Retrieval

5.1 Eye retrieval manual

K Bennett to check that all corrections have been made. J Armitage to send K Bennett email listing requested amendments.

**J Armitage/
K Bennett**

5.2 Eye retrieval by third parties

A review by A Ranson of eye retrievals throughout the UK before NHSBT became responsible for the Bristol and Manchester Eye Banks had found that while more than 50% were undertaken by the Eye Retrieval Schemes (ERS) and NHSBT Tissue Retrieval Teams there were many staff in hospitals retrieving eyes under third party agreements with the CTS Eye Banks. Some staff were retrieving only very occasionally, which raised the question of associated risks including training requirements, quality issues, and inconsistent completion of labelling and paperwork. Now NHSBT and ERS staff were retrieving over 90% of eyes. A training package is now available and third party staff completing this will be added to a register of eye retrievers and deemed competent to retrieve on behalf of NHSBT.

The eight ERS sites have been offered 3 year rather than one year contracts to improve stability.

6 NHSBT

6.1 Monitoring weekly activity

Tissue and Eye Services held a weekly teleconference to assess the availability of corneas and monitor stock levels in the Bristol and Manchester eye banks. The aim was to have 350 corneas in storage at any one time and to set a target of 10 eye donors per day in order to increase the number of corneal transplants to 4500 p.a. There had been a reduction in eye donation recently and 284 corneas were currently in stock at the time of this meeting. It was agreed that the stock levels and availability of corneas should be disseminated more widely.

K Bennett

K Shah raised the problem with coroners causing delays over giving consent for a donation to take place. K Bennett noted that this was also a problem elsewhere. K Shah was talking to the Chief Executive at Moorfields about contacting the Chief Coroner to resolve this issue.

6.2 Pre-cut DSAEK: uptake of service

F Carley reported that 141 pre-cut DSAEK grafts had been issued by Manchester Eye Bank in the 10 months from 23 July 2015 to 2 June 2016. The full annual figures would be presented by F Carley at the next OTAG meeting. East Grinstead and Moorfields issue approximately 150 and 200 pre-cut DSAEKs p.a., respectively. An audit at Moorfields for 2015 found that detachment rates had fallen from 20% to 11% since the eye bank pre-cutting service had started. Surgeons' increasing expertise also likely contributed to this improvement.

F Carley

6.3 New services: Eye Bank preparation for DMEK

Eye bank prepared tissue for DMEK is being validated by Bristol Eye Bank and the service will begin following relocation of the eye bank to NHSBT Filton. The eye bank is due to move at the end of June with tissue processing restarting at the end of July. The DMEK service is likely to commence late August or early September. This will mean that surgeons will be able to request pre-prepared tissue for DSAEK and DMEK in addition to tissue for PK, DALK and ALK. Trephine diameter is likely to be 8 mm initially but, once the service is established, it may be possible that surgeons could specify their preferred diameter. To be discussed at OTAG. Eye bank staff received training from Dr Sing-Pey Chow, who provided the clinical lead for this project until she left Bristol Eye Hospital to return to Australia. D Tole will take responsibility for training assessments of eye bank staff. Moorfields and East Grinstead eye banks are also planning to implement DMEK services.

6.4 Availability of corneas

K Shah reported that he had again been told that corneas unsuitable for PK/EK were not available when he requested a cornea for a Boston KPro procedure. K Bennett to discuss with the NHSBT eye banks and customer services.

K Bennett

7 Eye Bank Standards

7.1 Chlorhexidine trial

K Shah reported that the chlorhexidine trial at Moorfields had included 22 corneas with no evidence of risk to the endothelium. The loss of corneas caused by microbial contamination had fallen from 4-6% to 1-2%. The additional cost of the chlorhexidine was offset by the reduced loss of corneas. Mandeville Medical is supplying chlorhexidine, PVP-I and sodium thiosulphate. Once Bristol Eye Bank has relocated, a chlorhexidine trial will be started. K Bennett to contact Mandeville Medical to discuss supplies of reagents.

K Bennett

7.2 Training for slit lamp examination

The slit lamps have been delivered to Bristol and Manchester eye banks. Training by the supplier in their use is included in the cost. D Tole and F Carley to provide the clinical training to eye bank staff. J Armitage gave F Carley the TBI Slit Lamp Atlas, which has already been reviewed by D Tole, to evaluate its usefulness in the training of eye bank staff.

**F Carley/
D Tole/
Eye bank
staff**

7.3 Review endothelial cell count estimations

Frank Larkin, Chair OTAG Audit and Analysis Subgroup wrote to J Armitage concerning the reliability of endothelial cell density (ECD) estimates by eye bank staff as there appeared to be a systematic difference between the Bristol and Manchester eye banks. J Armitage has suggested two solutions. In the short term, a slide with 12 laser-etched images based on actual corneal endothelia used for the St Etienne project to determine the reliability of ECD estimates has been obtained from Gilles Thuret. Staff in all four eye banks will submit their respective ECD estimates for these 12 images to J Armitage, who will have the actual ECDs. In the longer term, the NAVIS Eye Bank Image Analysis system from Nidek would improve ECD estimates and consistency between the eye banks. The cost is approximately £8000. The Berlin eye bank has used this system for several years with success.

**J Armitage/
Eye bank
staff**

8 OTTSG

8.1 Report from OTTSG

This meeting took place on 13 April and D Tole summarised the minutes, which were still in draft, covering points not already discussed at the present meeting:

- Emergency corneas: need to monitor to make sure these are appropriate requests (i.e., for perforation, threatened perforation, severe infection, single eye).
- Re-Validation of qualifications – discussions with College
- Eye Retrieval manual: use of Povidone-iodine or chlorhexidine rather than alcohol skin preps for donor preparation. Could also flush ocular surface with ophthalmic preparations of Povidone-iodine or chlorhexidine rather than with just sterile saline
- Use of LASIK corneas for DMEK was approved.

- Payment by results (PBR) tariffs still have not been revised to reflect changes in surgical techniques and practice. NHS Monitor sets the tariffs and a College committee has been set up to review PBR payments across a range of ocular surgery procedures.

Age-matching was previously the norm with donor not being more than 30 years older than recipients. However, when OTAG approved the abandonment of age matching, it was agreed that donors of corneas for DALK should not be over 80 yrs of age and that extreme donor-recipient age differences (donors older than recipients) should be avoided. There was some discussion about age matching for recipient patients under 30 years old as there was a recent instance of a very young recipient being sent a from a 92 year old donor. J Armitage to investigate with Mark Jones the occurrence of extreme donor-recipient age differences over the past 5 years. There used to be a paediatric waiting list for children under 8 years old to try to direct corneas from young donors to these very young patients. This waiting list no longer appears to be operational. It was therefore suggested that whenever surgeons registered a paediatric patient for a corneal transplant, they should be asked to state a maximum donor age, bearing in mind the scarcity of donors under 30 years old and the waiting time. There is also the concern that children born after January 1996 ('Club 96' children), who should not have been exposed to BSE through the food chain, should, according to the SaBTO guidelines for reducing vCJD transmission risk, receive tissue from young donors (see Table 14.1, SaBTO Guidance, 2011). K Bennett mentioned that serum eye drops for paediatric patients were obtained from outside the UK since there have been 4 cases of vCJD transmission by blood. The risk of transmission of vCJD by cornea is, however, considered to be minimal. D Tole will write a letter to the paediatric ophthalmic surgeon representative on OTTSG and OTAG (Sus Biswas) asking for some guidance on these matters.

**D Tole/
J Armitage/
M Jones**

D Tole

8.2 Donor information provided to surgeons

J Armitage circulated to OTTSG the current donor information sheet distributed to surgeons with corneas, which contains much unnecessary information about cause of donor death and post-mortem times for tissue procurement and processing. At the previous Eye Bank Subgroup meeting, it was suggested that surgeons need to know only donor age and gender, the endothelial quality information (endothelial cell density, etc), and the procedures for which the eye bank considered the cornea to be suitable. So far as quality and safety are concerned, the surgeon simply needs to be assured that the donor selection and testing and initial microbiological testing of the cornea during organ culture meets the Red Book and College standards. This would bring ocular tissue in line with accepted practice for other tissues, haematopoietic stem cells, blood and blood products supplied by NHSBT and the other UK Blood Services. Only two surgeons responded with any comments, stating that they wanted all the current information included on the form either for teaching purposes or to be able to better inform their patients about the donor's background. These were not considered to be justifiable reasons and J Armitage will prepare a paper for OTAG.

**J Armitage/
D Tole**

9 **Single European Code**

9.1 Implementation of ISBT 128

K Bennet explained that, from April next year, all tissues would have to be labelled with the Single European Code (SEC), a 40 character long unique code for each tissue product. Since the SEC accepts ISBT 128 coding, already used

NHSBT and which can be used for ocular tissues, ISBT 128 is being implemented for ocular tissue and J Armitage has applied for, and obtained, the codes covering ocular tissues provided by NHSBT. These codes will be shared with Moorfields and East Grinstead. The SEC has to appear in eye readable form on the label and NHSBT will also include a 2D Datamatrix bar code. At present, all ocular tissue quality and safety information, including donor and recipient details for the purposes of traceability, and clinical follow up of transplants at 1, 2 and 5 years, is a function of the National Transplant Database and the UK Transplant Registry (NTxD). Unfortunately, the programming requirements for NTxD to generate ISBT 128 and the SEC are beyond current remits. However, the PULSE IT system used for blood and other tissues is already ISBT 128 compatible and there is therefore an imperative need for quality and safety aspects of ocular tissue to be transferred to PULSE while retaining the clinical follow-up functionality of NTxD.

J Armitage

10 European Cornea and Cell Transplant Registry (ECCTR)

The ECCTR is an initiative led by the European Society for Cataract and Refractive Surgery (ESCRS) to establish a European corneal transplant and ocular cell transplant registry. ESCRS have established a European registry for cataract and refractive surgery (EUREQUO). The partners include the European Eye Bank Association (EEBA), EUCornea and the three existing registries in the UK, Sweden and Netherlands. The EU is funding 60% of the project over the first three years and the kick-off meeting was held in Luxembourg on 11 May. This was attended by Dave Collett and Mark Jones for NHSBT and J Armitage for EEBA. The core data set is being compiled and it is anticipated that the existing registries will automatically upload data to avoid surgeons having to enter data twice into their national registries and the EU registry.

11 Council of Europe (CoE)

11.1 Guidance for the Quality and Safety of Tissues and Cells for Human Application

The 3rd edition of this T&C guidance is currently being drafted by the Council of Europe EDQM. J Armitage is co-chair of the drafting group, which includes with K Bennett and Keith Smith from NHSBT. There are 30 chapters covering generic quality and safety aspects and requirements for specific tissues and cells. The guide is due to be released for public consultation later this year.

11.2 Prohibition of financial gain

The Council of Europe's Oviedo Convention and the WHO's guiding principles on organ transplantation both prohibit the making of financial gain from human body parts. J Armitage is a member of an ad hoc CoE Committee on the implementation of this principle across the 47 members of the CoE.

12 AOB

K Shah announced that this would be his last OTAG Eye Bank Subgroup meeting as he was leaving Moorfields Eye Bank to return to his speciality of oncology. J Armitage thanked K Shah for his knowledgeable and extremely constructive contribution to the Subgroup.

13 Date of next meeting

Friday 18 November 2016 – venue NHSBT Birmingham New Street to be confirmed.