

**NHS BLOOD AND TRANSPLANT
ORGAN DONATION AND TRANSPLANTATION DIRECTORATE**

**OCULAR TISSUE ADVISORY GROUP MEETING HELD AT 12.30 PM
ON WEDNESDAY 25TH JANUARY 2017 AT THE ROYAL COLLEGE OF
OPHTHALMOLOGISTS, LONDON, NW1 2HD**

PRESENT:

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| Mr Derek Tole | Chairman |
| Prof John Armitage | Bristol Eye Bank and Head R&D-Ocular, NHSBT Tissue and Eye Services |
| Mr Mark Batterbury | Regional Representative, North West |
| Mr Kyle Bennett | NHSBT National Tissue Bank |
| Mrs Hazel Bentall | Lay Member |
| Mrs Fiona Carley | Manchester Eye Bank |
| Prof Dave Collett | Associate Director – Statistics & Clinical Audit, NHSBT |
| Mr Ewan Craig | Regional Representative – West Midlands |
| Ms Clare Ecuyer | Recipient and Co-ordinator Representative |
| Ms Helen Gillan | General Manager, NHSBT Tissue and Eye Services |
| Mr Nabil Habib | Regional Representative – South West |
| Ms Cathy Hopkinson | Statistics & Clinical Studies, NHSBT |
| Mr Parwez Hossain | Regional Representative – South West |
| Ms Zoe Johnson | Regional Representative – North East |
| Dr Nigel Jordan | East Grinstead Eye Bank |
| Mr Mark Jones | Statistics & Clinical Studies, NHSBT |
| Mr Vinod Kumar | Regional Representative – Wales |
| Mr Frank Larkin | Regional Representative – London |
| Ms Holly Mason | Marketing and Campaigns Manager, NHSBT |
| Ms Ulrike Paulus | Consultant Haematologist, NHSBT Tissues and Cells Donation and Transplantation |
| Mr Jeremy Prydal | Regional Representative - East Midlands |
| Mr Madhavan Rajan | Regional Representative – East of England |
| Ms Victoria Sudall | SNOD & EPSOD Representative |
| Mr Michael Tappin | Regional Representative – South East Coast |

IN ATTENDANCE:

| | |
|-------------------|----------------------------------|
| Mrs Anna Kepinska | Tissue & Eye Services |
| Mrs Kamann Huang | Clinical & Support Services, ODT |

ACTION

- 1 WELCOME & APOLOGIES**
Dr Iain Bryce, Mr Andrew Chung, Prof John Dark, Prof John Forsythe, Prof Sue Fuggle, Mr Vinod Kumar, Mr Damian Lake, Prof Johnny Moore, Ms Amanda Ranson, Ms Anne Sheldon, Ms Emma Winstanley and Mr Isaac Zambrano.
- 2 DECLARATIONS OF INTEREST**
 - 2.1 There were no declarations of interest.

ACTION

3 MINUTES OF THE OCULAR TISSUE ADVISORY GROUP – WEDNESDAY 29 JUNE 2016 – OTAG(M)(16)2

3.1 Accuracy

The minutes of the previous meeting were agreed as an accurate record following the inclusion of the amendments below:

Page 8, Item 9.1

- first line - “major adverse advents” to be amended to “major adverse events”.
- second line - “14 major adverse advents” to be amended to “13 major adverse events”.
- third line “preceding 6 months” to be amended to “preceding 5 months”.
- fourth line - “ 7 have been reported” to be amended to “6 have been reported”.

3.2 Action Points

Action points have been completed or are listed as an agenda item.

AP1 - AP12 Standard acknowledgement for electronic ordering/fax for eyes:

K Bennett reported that all orders by fax now are acknowledged. The email trail for organs is now well established and is working well. K Bennett encouraged the use of email using “nhs.net” which will also be more secure. He will look into setting up a more user friendly order form.

K Bennett

AP3 – Eye Bank Subgroup report: 3 June 2016. Review and update the Donor Information Sheet for submission to OTTSG and to OTAG for approval will be covered under Agenda Item 6.

AP7 – All three items have been completed.

3.3 Matters arising, not separately identified

There were no other matters arising.

4 OCULAR TISSUE ADVISORY GROUP

4.1 Chairman’s report

4.1.1 Update on PbR tariffs – OTAG(17)2

Following 3 years of campaigning for PbR tariffs to be raised in line with the UK corneal transplant service. A provisional update for 2017/18 is attached (Appendix A).

M Batterbury reported that Liverpool hospitals have returned to ‘block contracts’. Further clarification of the complexity of corneal procedure and tariff to be provided through the Royal College of Ophthalmologists’ Working Party.

M Batterbury

4.1.2 Referral to Treatment Times – 18 weeks

A problem was raised regarding meeting referral to transplantation times within the 18 week (RTT) timeframe. Currently the 18 weeks start at the time of referral from the GP to treatment. However time pressures occur when patients are referred from secondary to tertiary care for corneal transplantation. Additionally there is an intrinsic 6-8 weeks delay subject to tissue availability.

Discussion on RTT is to be based on the same procedure as for solid organs. An appeal will be lodged with Referral to Treatment (NHS England) for corneas to be treated like matched grafts.

D Tole

ACTION**4.1.3 Ocular Patient Group Meeting**

The Ocular Tissue Patient Group meeting took place on 9 November 2016. The minutes are attached (Appendix B).

4.1.4 Web-based UK follow up return forms

This was discussed at the OTAG Audit & Clinical Research Sub Group meeting held in the morning. D Tole reported that a provisional pilot study had been started entering follow up return forms on-line to test the system. This will now be extended to five other centres.

D Tole**4.1.5 Administrative support for OTAG and sub-groups**

Members thanked K Huang for her administrative support for the OTAG meetings to-date. OTAG transferred to Tissue and Eye Services under H Gillan on the 1 January 2017.

4.1.6 Filton Eye Bank Opening Ceremony

The next OTAG meeting will be held on Wednesday 14 June at 10.30 am at Filton, Bristol. The official opening ceremony of the Filton Eye Bank (already up and running) will be held around 12.30 pm in the afternoon. The recommendation was made to hold the OTAG Audit & Clinical Research Sub Group meeting 4 weeks beforehand i.e. around middle of May. F Larkin and M Batterbury suggested inviting a corneal transplant recipient prominent in sport or public life to attend.

**D Tole/
H Gillan****4.1.7 OTAG Chair**

D Tole has completed his 3 year term as Chair of OTAG which will now come up for renewal. Members were invited to apply. Members agreed at the meeting that they were happy for D Tole to complete another term for two years.

5 TISSUE AND EYE SERVICES (TES) REPORT**5.1 General Overview - OTAG(17)3**

- 5.1.1 H Gillan provided a detailed overview based on the presentation. Reasons for transferring Ocular to Tissue and Eye Services (TES) were highlighted. It was stressed that the Bristol Eye Bank was not fit for purpose when it was passed over to NHSBT. This has now a purpose built site in Filton that has been up and running since October 2016. Since H Gillan has been accountable for that part of the service the discard rate has improved and has gone down from 30 to 23% with more corneas now available. The next step is to increase the supply of pre-cut corneas.

F Larkin and N Jordan raised their concern that the NHSBT retrieval teams have for some time now been retrieving eyes from Eye Only donors in the areas historically served by Moorfields and East Grinstead respectively. Although this may have increased NHSBT retrieval figures it is at the expense of those being retrieved by Moorfields and East Grinstead and risks destabilising the grafting activities at these two centres. The retrieval of Eye Only donors in the East Grinstead area has been discussed previously with K Bennett who has agreed that they should be referred to East Grinstead and not be retrieved by NHSBT.

The SNOD/EPSOD Lead agreed that she was aware that Eye Only donors in the East Grinstead area had been attended by NHSBT teams. N Jordan also requested information on the completion ratio of referrals made from centres in the East Grinstead area to NHSBT and questioned whether referrals could be made directly to East Grinstead as has been the case in the past.

ACTION
K Bennett

K Bennett agreed to review the system and look at changing it back if it wasn't working.

It was highlighted that the date of when the patient is listed should be entered on the Request Form for the purpose of data collection. Ten donors are required per day, the average is currently 8.5 donors per day.

5.2 Eye Retrieval Schemes (ERS)

5.2.1 Tissue and Eyes Strategy

H Mason outlined the following points to members in her presentation to increase eye donation:

- NHSBT working with a marketing consultancy undertaking in depth interviews with 4 key stakeholders and others.
- Willingness to donate eyes, 56%, is lower than for other organs
- Eye donation is the most challenging. The strategy is to create a culture to increase awareness and therefore consent. The aim is for 70% (equates to kidney donation).
- There will be a 9 month pilot (currently at planning stage) to test the effectiveness of marketing and communications activity with activity focused in and around the Referral Super Centres with the message to focus on the donation of sight rather than eyes or corneas.
- The marketing strategy will be on public education, partner outreach and hospital communication and we will ask the ambassadors to spread the message. Social media is accepted to be the best channel of communication. Eye donation is not 'life saving' but is 'life changing'.
- We need local donor family experiences for the public to relate to. Therefore work with hospitals to get real life story and pictures (using Intensive Care Unit (ICU) photo wall mounts and an ICU family feedback book). Members were asked to share any recipient/donor stories with H Mason. Nigel Jordan (E Grinstead) reported that they are already doing something similar on a local level which he will share with H Mason. F Larkin (Moorfields) have produced a 5 minute movie depicting corneas as a gift which he will pass onto H Mason. Each of the regional representatives are to email a donor/recipient story from their own area to H Mason.

N Jordan

F Larkin
Centre Reps

5.2.2 Update – OTAG(17)4

- The eye retrieval kits supplied by NHSBT TES have been updated and now also include the unique ISBT 128 barcode donation label. This is a statutory requirement to meet the implementation of the single European coding by 1 April 2017.
- All eye retrievers have ben retrained following changes to the eye retrieval kits and on the operating procedure.
- A number of corrective and preventative actions have been put in place following an increase in adverse events since December 2016 regarding the use of 'expired' eye retrieval kits by third party eye retrievers
- Progress is being made with the Partner hospitals in the Eye Retrieval Schemes.
- NHSBT TES Retrieval teams facilitated 54% of all eye retrievals.

5.2.3 Questionnaire on imported corneas to transplant centres – OTAG(17)5

A letter from D Tole and H Gillan has been sent to all the Ophthalmic Surgeons on 17 January 2017 asking them to provide the number of imported

corneas for the past calendar year for their unit. A Kepinska is compiling a spreadsheet with all the feedback for presentation at the OTAG meeting on 14 June 2017.

ACTION
A Kepinska/
D Tole/
H Gillan

5.2.4 **Update on National Referral Centre/"Super Centres" – OTAG(17)6**

K Bennett reported that it is believed that 90 corneas per week are required to meet current UK demand. At present NHSBT are supplying 80-85 corneas per week. In the past excess corneas have been exported but NHSBT are not currently permitted to do this. The transplant rate per capita in the UK is believed to be 2-3 times lower than the US; and 1.5 times lower compared to Sweden. Moorfields undertook 844 corneal transplants (23% imported) in 2016. Ideally the UK should aim for self sufficiency.

NHSBT are working with the National Referral Centre and Super Centre strategy to generate sufficient referrals to meet the demand.

5.2.5 **Draft corneal Thank You cards – OTAG(17)7**

Draft corneal Thank You cards were presented to Members. A pilot scheme for the cards will be undertaken to gauge the response rate following transplant. N Habib stated that they currently give bracelet to patients.

Post Meeting Note

A trial will be undertaken in North Wales as well as in Bristol.

5.3 **TEPSOD**

5.3.1 **Update**

V Sudall informed members of the introduction of a new two day training scheme. This involves moving a trained SNOD into a specialist requestor only role to speak to families to build up expertise. A trial has been underway since last April with the aim for every team to have 2 to 3 trained specialists to see if this improves the consent rate. The biggest problem is still families refusing consent for donation around 43%. An update will be given at the next OTAG meeting in June. A Kepinska to list as an agenda item. Not much improvement has been seen after 6 months but we hope to see a result after 1 year.

V Sudall/
A Kepinska

5.3.2 **TEPSOD activity – OTAG(17)8**

Key points highlighted from the data presented by M Jones were:

- There has been a continued fall over the last eight years in organ donors that were medically suitable to donate eyes from 93% in 2008/9 to 65% in 2016/17.
- Since 1 April 2008 there has been an overall increase mainly due to DBD (donation after brain death) donors for eye donation from 37% to 40% with very little change for DCD (donation after circulatory death) donors.
- Family refusal remains the main reason for non-eye donation followed by medical reasons.

5.4 **Eye Banks**

5.4.1 **Eye Bank sub-group report: 18 November 2016 – OTAG(17)9**

The Bristol and Manchester Eye Bank is now under NHSBT. The question was raised regarding the continuation of the Eye Bank sub group; the suggestion is that a sub group would sit better within OTTSG rather than OTAG. J Armitage to look into this.

J Armitage

ACTION

Other points highlighted were:

- Tissue Donor Selection Guidelines: Further input required from microbiologists and on neurological conditions to include Alzheimer and CJD. This will then be submitted to OTTSG.
- Eye Bank preparation for DMEK. J Armitage reported on a study using two corneas from the same donor where there are medical contraindications to corneal transplantation. The endothelial cell density (ECD) of both corneas of each pair will be measured before one cornea is placed into dextran medium and the fellow cornea undergoes Descemet Membrane (DM) stripping, leaving the graft attached at the centre. The ECD of the DM-stripped cornea is measured again before it is placed into dextran medium. The ECD of both corneas is then measured after 4 days. If the study is validated then it is hoped to implement a pilot early in 2017, which would follow a similar format to that for DSAEK. E Hollick suggested that off-centre attachment (i.e. a peripheral hinge) would be advantageous based on her experience. It would also mean that the eye bank would no longer need to trephine the ocular tissue, leaving the final decision of trephine diameter to the surgeon in theatre. During the pilot the usual fee for a cornea would apply but there would be no fee for the DMEK preparation.
- Training for slit lamp examination. Training programme to be discussed for the use of slit lamps at Bristol Eye Bank and Moorfields.
- The 3rd edition of the Council of Europe Guide to the Quality and Safety of Tissues and Cells has been drafted for consultation. J Armitage is Co-Chair. A Chandrasekar will review the document. It was suggested a rep from OTAG to look at the ocular parts of the document to feed into SAC TCTP.
- Eye bank analysers will be ordered by the end of the financial year, 31 March 2017, to improve the accuracy of endothelial cell density count. The cost is about £10k per analyser.

5.4.2 Update on pre-cut lamellar service – OTAG(17)18

A pilot study was undertaken involving 32 surgeons completing a questionnaire (four questions) on the quality of pre-cut tissue for DSAEK. Feedback was received from 20 surgeons indicating 19 out of 20 surgeons were satisfied. Five surgeons reported problems with the tissue during surgery. Three surgeons reported they would not be using further pre-cut tissue; one owing to imminent retirement.

F Carley to liaise with M Jones on providing 12 month follow up data.

**F Carley/
M Jones**

5.4.3 DMEK Update

Refer to agenda item 5.4.1.

6 THE ROYAL COLLEGE OF OPHTHALMOLOGISTS OTTSG REPORT – 16 November 2016 – OTAG(17)10

6.1 A summary of some of the points raised were:

- Donor Allocation: There are concerns regarding ages of donors to recipients regarding paediatrics cases. It was suggested that NHS BT could ask if the upper age limit be exceeded to accept corneas in specific cases. There should ideally be age matching to a maximum of 30 years.

ACTION

- Surgical Skills Training: Request to Training Committee for ophthalmic trainees to fulfil the Surgical Skills SS13. OTTSG and NHS BT are both in favour of this.
- Consent Form: Wording on the form has been revised to allow use for research if the tissue is not suitable for transplant.
- Discussion on whether there should be a separate paediatrics form or an appendage to fit in with the current NHS BT forms. This will be discussed in more detail by a core group of individuals and re-raised at OTTSG.

A copy of the full OTTSG minutes not available at the time of the meeting are attached (Appendix C).

7 STATISTICS & CLINICAL STUDIES REPORT

7.1 Conference presentations, current and future work – OTAG(17)11

A report summarising the current and future work undertaken by NHSBT was presented to members. Since the last meeting in June there have been two further publications.

7.2 Audit Clinical and Research subgroup report: 25 January 2017

A summary of the points discussed were:

- Five year EK outcomes to be recorded.
- DMEK: a total of 279 had been registered since July 2014 (12% of all EKs). Outcomes were poor by comparison to DSAEKs. M Jones will present this at the Bowman Club's meeting.
- Regrafts rates are high and we are taking this forward to look at patients with PK for failed DSAEK and DMEK.
- Ongoing work looking at transplanting male donor corneas into female recipients followed by a clinical trial.
- We have asked John Armitage, in his capacity as NHSBT R&D director, to join the Sub Group. Andy Frost (Torbay) will replace Johnny Moore.

7.3 Form return rates –OTAG(17)12

Data on the transplant record forms for one, two and five year follow up were analysed for the last 10 years from April 2006 to March 2016. The overall return rate was 96% dropping year on year.

P Hossain reported that a fellow has been taken on at their unit for 6 months to look at the form returns; a backlog of 500 forms. These will be coming through. D Tole stated that an amnesty could be offered for 5 years follow up forms where 12 and 24 month data has not been submitted. Moorfield's and St Helen's have increased their return rates significantly following individual letters being sent out.

8 CLINICAL GOVERNANCE

8.1 Governance sub group report – OTAG(17)13

The Governance Sub Group has been reconvened. The meetings will aim to capture governance issues at all four UK eye banks.

U Paulus presented a report updating members on major/critical incidents and outlined events reported to the HTA, SARE forms and general developments.

The following two points were highlighted to members:

- to ensure the Donor reference number was entered on the Ocular Tissue Transplantation Adverse Reactions/Event form, and

ACTION

- to return unused tissue in the original container to the issuing Eye Bank for investigation and stating whether the patient was anaesthetised. U Paulus to submit a revised form for comment.

U Paulus**8.2 SAER notification – OTAG(17)14**

In the absence of a paper no report was given under this item.

8.3 Corneas issued but not used

Concern was expressed over the increase in the number of corneas not used; 43 corneas issued but not used per month. It was highlighted that we need to know the reasons for non-usage and which surgeons are not providing this information. K Bennett to validate the reasons for non-usage and obtain figures for the re-allocation of corneas. U Paulus to raise the issue of non-usage of corneas at the Governance Meeting. Each regional representative is obligated to inform their own transplant centre of the high numbers of corneas not used and look into what is not used. K Bennett to compose a letter (with D Toole and M Batterbury's signature) to transplant centres to validate their data and to look at any trends. The message should capture any corneas damaged by a surgeon via a SAER.

**K Bennett
U Paulus****K Bennett****9 SAC-TCTP report (The Standing Advisory Committee on Tissues and Cells Therapy Products) – OTAG(17)17**

A paper was presented by J Armitage on recommendations on measures to protect patients from acquiring hepatitis E virus via transfusion or transplantation.

10 The Single European Code (SEC) for tissues and cells

To comply with the statutory Single European Code, labels will change and have a 40 digit code to be implemented on 29th April 2017. The left hand side of the label will contain information about the tissue itself e.g. its clinical use, cell count, when it was collected and expiry date. The right hand side of the label will capture other information e.g. requests from other surgeons.

11 ANY OTHER BUSINESS

No issues brought up.

12 FOR INFORMATION

The following papers were presented to members for information:

12.1 December 2016 Activity Report – OTAG(17)15**12.2 ICT Progress Report: 16 September 2016 – OTAG(16)16****13 DATE OF NEXT MEETING:**

Wednesday 14th June 2017 – 10.30 am Filton, Bristol. The Opening Day for the Filton Eye Bank will be held in the afternoon at 12.30 pm.

January 2017