NHS BLOOD AND TRANSPLANT
ORGAN DONATION & TRANSPLANTATION DIRECTORATE

MINUTES OF THE THIRTY SECOND MEETING OF THE LIVER ADVISORY GROUP HELD ON WEDNESDAY 22ND NOVEMBER 2017 LONDON

PRESENT:

Prof John O'Grady	**Chairman**
Prof Derek Manas	Deputy Chair, BTS Rep and Surgeon, The Freeman Hospital Newcastle upon Tyne
Dr Varuna Aluvihare,	Physician, King's College Hospital
Ms Helen Aldersley	Recipient Co-ordinator Representative
Dr Elisa Allen	Statistics and Clinical Studies, NHSBT
Mr John Asher	Medical Health Informatics Lead, ODT
Mr Magdy Attia	Surgeon, St James's University Hospital, Leeds
Mr Andrew Broderick	Transplantation Support Services, ODT
Mr Chris Callaghan	National Clinical Lead for Organ Donation (Abdominal)
Mr John Crookenden	Liver Patients' Transplant Consortium
Dr James Ferguson	Physician, Queen Elizabeth Hospital, Birmingham
Prof John Forsythe	Associate Medical Director, NHSBT
Prof Peter Friend	Chair of Bowel Advisory Group
Mr Paul Gibbs	Surgeon, Addenbrooke's Hospital
Prof Nigel Heaton	Surgeon, King's College Hospital, London
Mr Emir Hoti	Surgeon, St Vincent's University Hospital, Dublin
Dr Diarmaid Houlihan	Physician, St Vincent's University Hospital, Dublin
Dr Mark Hudson	Physician, Freeman Hospital, Newcastle
Mr Ben Hume	Assistant Director, Transplantation Support Services, NHSBT
Mr Charles Imber	Surgeon, Royal Free Hospital
Dr Edmond Jessop	Public Health Advisor, NHS England
Dr Rebecca Jones	Physician, St James's University Hospital, Leeds
Dr Joanna Leithead	Physician, Addenbrooke's Hospital, Cambridge
Ms Wendy Littlejohn	Recipient Co-ordinator Representative
Ms Sarah Matthew	Lay Member
Dr Indra van Mourik	Deputy for Dr Susan Beath, Birmingham Children's Hospital
Prof Paolo Muiesan	Surgeon, Queen Elizabeth Hospital, Birmingham
Ms Jacki Newby	Head of Referral and Offering, NHSBT
Mr James Powell	Surgeon, Royal Infirmary, Edinburgh
Ms Laura Ramsay	Recipient Co-ordinator
Dr Sanjay Rajwal	Paediatric Hepatologist
Ms Susan Richards	Organ Donation Representative, Eastern and Midlands
Dr Ken Simpson	Hepatologist, Royal Infirmary of Edinburgh
Ms Alison Taylor	Co-Chair of Liver Patients' Transplant Consortium
Ms Rhiannon Taylor	Statistics and Clinical Studies, NHSBT
Dr Douglas Thorburn	Physician, Royal Free Hospital and BLTG Rep
Ms Lynne Vernon	Lay Member
Mrs Sarah Watson	Highly Specialised Services, NHS England
Mr Stephen Wigmore	BTS Vice President

IN ATTENDANCE:

Mrs Kamann Huang	Clinical & Support Services, ODT

ACTION

APOLOGIES & WELCOME

Dr Susan Beath, Prof Sue Fuggle, Dr Tassos Grammaticopoulos, Mrs Judi Rhys, Mr Anthony Snape and Mr Mick Stokes.

1 DECLARATIONS OF INTEREST IN RELATION TO AGENDA – LAG(17)24

1.1 There were no declarations of interest.

2 MINUTES OF THE MEETING HELD ON 10 MAY 2017 - LAG(M)(17)1

2.1 **Accuracy**

2.1.1 The minutes of the previous meeting were agreed as an accurate record.

2.2 **Action points – LAG(AP)(17)2**

2.2.1 All action points have been completed. Those with a Verbal Report are listed with an update below or are referred to as an Agenda Item.:

AP2 - Detailed analysis of incidents for review - Reporting of infections from perfusion fluid around organs
A joint letter, working with the Governance team and Ines Ushiro-Lumb is planned in the next few weeks, with advice about the organisms and the process for reporting.

AP6 – Peer Review
Refer to agenda item 7.2.

2.3 Matters arising, not separately identified

2.3.1 There were no matters arising.

3 GOVERNANCE ISSUES

3.1 Non-compliance with allocation

3.2.1 There were no cases of non-compliance with the allocation of livers reported except for an issue regarding super urgent liver allocation out of sequence. Refer to agenda item 3.5.

3.2 Detailed analysis of incidents for review – LAG(17)25

3.2.1 Following the report of an incident regarding the time taken over vessel allocation for the split of a liver and a separate kidney/pancreas transplant leading to the liver not being split, D Manas agreed to confirm the approach to take regarding whether vessels should always go with the liver as discussed at NRG following consultation with both PAG and LAG members. Centre representatives to remind their centres of the protocol following confirmation. The priority is the left lateral segment is offered for a paediatric patient and splitting must not be stopped because an adult patient requires a whole liver. Should there be any doubt the decision should be agreed between a LAG and a PAG surgeon and not left to a junior clinician. This has been agreed. J Forsythe agreed to remind centre representatives of the document in place for this. **D Manas**

ACTION

3.3 Incidents under review

3.3.1 Points discussed are as follows:

1. Learning points from incidents have been agreed to be shared across transplant centres in a timely manner. This is already happening.
2. Following two incidents around a living donor liver transplant. D Manas led an External Review team at the centre. A report has been sent to the hospital concerned and the Medical Director. In the last few days a NHS England regional representative has asked to meet with the hospital representatives concerned. A Shared Learning document, as a précis of the full report, has been prepared as a draft. Once the hospital concerned agrees the report the Shared Learning document will be distributed to LAG members.

3.4 CUSUM

3.4.1 CUSUM Triggers

J Forsythe reported that a centre had triggered a CUSUM recently. The centre had noted the likelihood of the trigger and contacted him to ask for an External Review which will take place on 16th January 2018.

Discussion took place regarding members of the external teams for the review of such incidents; how they were chosen and the involvement of NHSE or another commissioner.

The Medical Director chooses the team in liaison with the Chair and Vice Chair of LAG. Members are drawn from LAG unless external expertise is required. The final report lists the members of the team.

There was also discussion regarding the availability of the report from any investigation; as noted above, shared learning will be distributed to all members of LAG.

3.4.2 Recalibrated CUSUM monitoring – LAG(17)26a & b

3.4.2 **LAG(17)26a**

Update of baseline period for estimating centre-specific mortality rate and chart limit. The following changes to the CUSUM monitoring were agreed: **E Allen**

a. The baseline period will be updated to 1 January 2012 to 31 December 2015;
b. The charts will monitor transplants performed from 1 January 2016 instead of 1 January 2012 which is currently used;
c. The chart limit will be changed to 2.0, from 2.5, to increase sensitivity;
d. Adult centres will be monitored against both centre-specific mortality rate and the national rate rather than only centre specific rate. Only the national rate will be used to identify a signal and the comparison against a centre's rate will be for information only.
e. Paediatric centres will be monitored against the national mortality rate due to the very low number of deaths within 90 days at the 3 paediatric centres.
f. These changes will be implemented from December 2017.

LAG(17)26b

The current CUSUMs only monitor patient status (alive/dead) at 90 days post-transplant and does not take into account the actual survival time post-transplant. Following discussion, it was agreed:

ACTION

a. Statistics and Clinical Studies will decide on the outstanding methodological issues, e.g. use of modal or median values for imputation of missing values,
b. LAG endorsed the table of factors presented to be included in risk adjustment,
c. Target implementation is Spring 2018 but this could be affected by the introduction of the new liver offering scheme.

3.5 SU liver allocation out of sequence – LAG(17)27

3.5.1 J Newby raised two cases of the liver being requested to be allocated to super urgent patients out of sequence and what the viewpoint of members was regarding payback. LAG members agreed that there should not be a payback system.

4 ACTIVITY, ORGAN UTILISATION AND OUTCOME MONITORING

4.1 Liver splitting activity – LAG(17)28

4.1.1 Data presented showed a reduction in the percentage of livers split in the first half of 2017/18 compared to levels achieved in preceding periods. J O'Grady asked the question whether liver splitting was paediatric driven and what was the paediatric mortality rate on the waiting list?

N Heaton commented that over the last 2 years the number of paediatric patients on the waiting list has varied between the three paediatric transplant centres; Birmingham undertake living liver transplantation which has reduced their mortality waiting list. D Manas reported that some of the split livers offered in the last 6 months for paediatric recipients have not been accepted. Liver splitting at King's has increased and tends to be undertaken at night. If there is no paediatric recipient, the left lobe should go to adult transplant centres. Other issues raised were:

- which centres have the expertise to split between the left and right lobe. D Manas stated that the skill required to split a full left and right lobe is very different from current splitting. The technique of splitting will vary as there is no agreement. At King's when the liver is split, the adult centre gets the full portal vein and artery which is different from splitting with a short vein and artery.
- transportation of the right lobe does not hold up as well as the left lobe, and
- D Manas reported that training offered previously was not taken up by centres and questioned whether this should be addressed in the Clinical Service Evaluation.

E Allen to report on paediatric waiting list size, waiting list mortality and transplant activity. Look at whether it is feasible to show where there has been an increase in the use of "no suitable recipient" as a reason for not splitting and is there a decrease in demand for paediatrics requiring a liver. **E Allen**

4.2 Activity and organ utilisation monitoring (dashboard) – LAG(17)29

4.2.1 The most recent dashboard report for adult patients covering transplant activity for 1 July to 30 September 2017 was circulated in November 2017. Members were invited to send any comments to statistical.enquiries@nhsbt.nhs.uk

The dashboard reports for paediatric patients have been suspended until further notice.

ACTION

4.3 Combined liver and kidney transplantation – LAG(17)30

4.3.1 A new process was introduced on 5 May 2015 following concerns about patients having to wait a longer time for a combined liver/kidney transplant. The issue now is how this process will fit in with the new national liver offering scheme.

It was agreed that, in line with current policy to account for the fact that DBD livers will cease to be offered zonally in future to elective patients but nationally, ODT Hub Operations will withhold from offering one kidney if any of the three top ranked liver elective patients require a kidney. If there is no need for a kidney they can go ahead and offer the kidney. This will be actively reviewed through the Monitoring Committee. This will be put in place for March 2018 in preparation for the new national liver offering scheme. **J Newby/ E Allen**

4.4 UK transplant registry analysis of retrieved and not transplanted livers – LAG(17)31

4.4.1 One factor in recent years for organs not being utilised is due to donors being older and with a higher BMI. This has led to more marginal organs being offered for transplantation. Overall livers retrieved and not transplanted remain stable but are increasing slightly.

Comments included: J O'Grady stated that Table 4 must be corrected and data must not be published without strict quality checks. C Callaghan suggested taking a sample of livers not used to other centres to establish if these livers could be used. N Heaton stated that, ultimately, the non-use of livers is driven by marginality caused by cold ischaemic times and not attributes of the donor per se. He called for an organised national programme to address this issue.

<u>Amendments to data before being published:</u> **E Allen**

- Table 1. Bold fonts to be rectified.
- Where appropriate, state that statistical significance is not equal to clinical significance
- Table 4 – percentages to be corrected.
- Page 10, Point 22. '*Birmingham and Cambridge*' should read ***'Birmingham and King's*** have the highest median DLI.
- When discussing the high rate of retrieved and not transplanted livers achieved by King's, a note should be added saying that King's take an open view to look at the liver before turning it down.

4.5 Reasons for liver offer decline – LAG(17)32

4.5.1 J Asher reported that Hub Operations list up to three reasons from a drop down menu for declined organ offers. The proposal is to look at a more accurate way of recording and suggested 5 different categories:

1. Donor unsuitable.
   Note: Number (3) in this category needs to be redefined. **J Asher**
2. Organ unsuitable
3. Organ unsuitable for named recipient
4. Recipient unsuitable, and
5. Logistical issue e.g. no bed being available.

Members agreed to accept the above categories.

ACTION

5 National Offering Scheme

5.1 Timescale to Implementation

5.1.1 B Hume informed members that in preparation for its implementation date on 19 March 2018 work is being undertaken on developing the scheme and transplant list developments will be rolled out week commencing 11th December. There will also be training of specialist nurses and transition of liver offering from SNODs to Hub Operations.

5.2 Communication Strategy - 14 November 2017

5.2.1 The following points were raised:

- Following the stakeholder meeting on 14 November 2017 separate meetings will be offered with each transplant centre. The agenda will be locally developed and focussed on what is locally needed in day to day management of patients in light of the new offering scheme.
- J O'Grady stated that the impetus is now with the centres and it is up to them to request these workshops to be held at their transplant centre. **Centre Reps**
- Discussion turned to the reporting of sequential data for elective liver recipients on the waiting list, which will be required in the new offering sequence. Comments were made regarding the monitoring of the completeness of data. The Chair gave reassurance that this is being addressed.
- A stakeholder group with clinicians and recipient coordinators will be held shortly.
- The question of whether NHS England will increase their level of financial support for the increased workload transplant centres faced by the introduction of the new scheme was raised e.g. regular submission of sequential data for elective patients on the waiting list. E Jessop reported that the Trusts signed with NHS England to agree to the specification so the issue is not finance.

5.3 Post implementation monitoring – LAG(17)33

5.3.1 The proposal is to initially provide enhanced monitoring following the new National Liver Offering Scheme with a regular three month report, then at six months and then on a yearly basis if appropriate. The proposal was endorsed by LAG.

It was requested that combined liver/kidney waiting list and activity data is monitored outside the report produced by the Monitoring Group. NHSBT will take forward the constitution of this Group, in collaboration with Core Group.

5.4 Changes to registration form and sequential data submission process – LAG(17)34a & b

5.4.1 The draft registration form was presented to members for information and is not expected to change. Guidelines for form completion will be circulated by Hub Information Services.

Post meeting Note
The Guidelines have been circulated to all the recipient co-ordinators and visits to transplant centres have been undertaken.

ACTION

6 ADULT TO ADULT LIVE DONOR TRANSPLANT

6.1 D Manas reported that the proposal produced by the Working Group has been submitted to NHS England. He will also rewrite the document as a service specification. The proposal is to change the living donor programme nationwide and look at how to finance this. Information will be used from the Clinical Retrieval Group (CRG). **D Manas**

7 LIVER TRANSPLANT COMMISSIONING

7.1 NHS England

7.1.1 S Watson informed members that most centres are funded similarly per transplant. Last year, there was growth in five of the centres with the other centres being more stable. Following discussions investment has been made to four centres; the other centre is aware of this. Commissioning is still being drawn up for London. N Heaton commented that there is no transparency in funding per centre with funding being done en bloc. He believed that recommendations made have not been acted on and therefore he has no confidence in this respect.

7.2 Peer Review

7.2.1 The draft report was presented at BLTG with the national report expected to be released in January 2018. Transplant centre representatives had no objection to their own own centre reports being shared with other transplant centres. However, as a formality, it was agreed that LAG centre representatives will write to their corresponding Trust Boards to ask for approval to share, and inform S Watson. K Huang to email the centre representatives. **Centre Reps / K Huang**

J Crookenden stated that it was poor to wait until 2018 to get the national peer review report. The Peer Review is not about finding fault but about increasing and improving care to patients.

7.3 Living related transplants

7.3.1 D Manas reported that there were no new developments since the last LAG meeting.

8 CLINICAL SERVICE EVALUATIONS

8.1 HCC downstaging – LAG(17)35

8.1.1 There were no issues of concern in this report.

8.2 Acute alcoholic hepatitis (AAH) – LAG(17)36

8.2.1 The programme for AAH, led by A Gimson and J O'Grady, received a high level of support when first introduced. In practice, the service evaluation has served very few patients. It was commented that survival for AAH patients has improved dramatically with medical management. Following advice it was agreed to close the service evaluation. **E Allen**

9 HEPATITIS DAAs AND IMPACT ON DONATION

9.1 A new group is developing this option on a national basis. There is currently little data published in this area of donation. However the Group felt this

ACTION

avenue of donation should be pursued. The final document is being put together which has so far been positive and well received.

NHS England stated that this category of patients would not currently be funded for DAAs so any developments made would need to take this point on board.

10 CENTRALISED EXPLANT REVIEW, SU LISTING & HCC

10.1 There is currently no monitoring with explant data in two areas of privileged access to organs or strict eligibility. The proposal to develop an FTWU with hepatologists to develop an explant review process for all patients super-urgently listed or with hepatocellular carcinoma was unanimously accepted.

11 STATISTICS AND CLINICAL STUDIES (SCS) REPORT

11.1 Summary from Statistics and Clinical Studies – LAG(17)37

11.1.1 Points noted from the paper were:

- R Johnson has been appointed Associate Director of SCS as successor to Prof. D Collett following his retirement.
- All new and updated reports are available on the ODT clinical website.
- Funding is in place for two clinical fellows; one working on cardiothoracic transplantation in Papworth and the second post is currently vacant to work in abdominal organ transplantation.
- NHSBT will be recruiting for a clinical fellow to work alongside C Callaghan on organ utilisation to start in 2018.

Members congratulated E Allen and R Taylor on receiving the NHSBT Excellence in Research 2017 Award for their contribution to research in the new liver offering scheme.

12 DCD LIVER SCREENING – LAG(17)38

12.1 A letter has been sent to all liver and kidney transplant centre directors, clinical leads and transplant co-ordinators informing them of some changes to the DCD Donor Assessment and Organ screening process in the UK. A liver DCD screening pilot will go live on the 1 December 2017 on a trial basis. The screening process will be piloted for 3 months and then reviewed by the Liver Advisory Group.

13 REGISTRATION, OFFERING AND DATA COLLECTION OF DUBLIN PATIENTS

13.1 E Allen will continue to work with Hub Information Services and the Dublin transplant centre to ensure that the new liver offering scheme does not impact the arrangements currently in place between the Republic of Ireland and the UK. **E Allen**

ACTION

14 MULTI-VISCERAL & COMPOSITE TISSUE ADVISORY GROUP (MCTAG)

14.1 Report from the Multi-Visceral & Composite Tissue Advisory Group Meeting - 11 October 2017

14.1.1 In the absence of P Friend, the main points discussed at the last MCTAG meeting are listed below:

- The National Bowel Allocation Scheme has been recoded to permit the maximum donor weight, reported at patient registration, to be used when selecting patients for intestinal offering.
- Looking at developing a separate UK Intestine Transplant Recipient Quality of Life form for paediatrics.
- Looking at drawing up two documents: a patient information document and consent for intestinal transplantation for paediatrics.
- S Kay presented to MCTAG for the first time on hard/arm transplantation.

14.2 Simulation for adult patients weighing more than 35 kg with a restricted abdominal cavity – LAG(17)39

14.2.1 A change was requested to give paediatric status to adult intestinal patients weighing more than 35 kg but with a restricted abdominal cavity. Following simulations undertaken by Statistics and Clinical Studies, there was no disadvantage to intestinal patients but evidence of potential disadvantage was found for two liver patients. LAG agreed that this is acceptable. P Gibbs, Addenbrooke's transplant centre, reported that Addenbrooke's does not require this arrangement any more.

A query was raised by P Gibbs regarding not all retrieval teams being able to retrieve fascia. Action has already been taken regarding this with HTA.

15 ANY OTHER BUSINESS

15.1 Transplant centres accepting multiple livers simultaneously

Refer to agenda item 3.2.

15.2 QUOD Leaflet

Post meeting note:
Following communication with the Quality Manager, S Richards confirmed that the QUOD leaflet documents (References INF1409 and INF1410) on the website and on the NHSBT controlled document library do state that the patient should contact the Clinical Team rather than the SNODs.

16 DATE OF NEXT MEETING:

Wednesday 2 May 2018, 12 Bloomsbury Square, London
Wednesday 21 November 2018, 12 Bloomsbury Square, London

17 FOR INFORMATION ONLY

The following papers were attached for information to members:

17.1 **Transplant activity report: October 2017 - LAG(17)40**

17.2 **Group 2 Transplants – LAG(17)41**

ACTION

17.3 **Outcome of appeals – LAG(17)42**

17.4 **Annual report on Liver Transplantation – LAG(17)43**

17.5 **Minutes of the Multi-Visceral & Composite Tissue Advisory Group meeting: 15 March 2017 - LAG(17)44**

17.6 **Minutes from the National Retrieval Group: 12 July 2017 - LAG(17)45**

17.7 **Update on Patient Consent Scheme - LAG(17)46**

17.8 **QUOD statistical reports - LAG(17)47**

New Appointments in NHSBT

- Dr James Griffin – Clinical Director for Therapeutics – 1 April 2017.
- Ms Rachel Johnson appointed AD of Statistics and Clinical Studies – 3 July 2017 replacing Prof Dave Collett's retirement (29 June 2017).
- Ms Suzanne Hunter, AD of Workforce – September 2017.

Organ Donation & Transplantation Directorate **November 2017**

Administrative Lead: Kamann Huang