NHS BLOOD AND TRANSPLANT
ORGAN DONATION & TRANSPLANTATION DIRECTORATE

MINUTES OF THE THIRTY THIRD MEETING OF THE LIVER ADVISORY GROUP HELD ON WEDNESDAY 2ND MAY 2018 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
Mr John Asher	Medical Health Informatics Lead, ODT
Mr Magdy Attia	Surgeon, St James's University Hospital, Leeds
Dr Susan Beath	Physician, Paediatric Hepatologist, Birmingham Children's Hospital
Mr Andrew Broderick	Transplantation Support Services, ODT
Mr Chris Callaghan	National Clinical Lead for Organ Utilisation (Abdominal)
Dr James Ferguson	Physician, Queen Elizabeth Hospital, Birmingham
Prof John Forsythe	Associate Medical Director, NHSBT
Prof Peter Friend	Chair of Bowel Advisory Group
Dr Alex Gimson	Physician, Addenbrooke's Hospital
Dr Tassos Grammaticopoulos	Physician, King's College Hospital, London
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
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
Prof Paolo Muiesan	Surgeon, Queen Elizabeth Hospital, Birmingham
Ms Lisa Mumford	Statistics and Clinical Studies, NHSBT
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 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
Mrs Sarah Watson	Highly Specialised Services, NHS England

IN ATTENDANCE:

Mrs Kamann Huang	Clinical & Support Services, ODT
Ms Michelle Hunter	Observer
Ms Maria Ibrahim	Observer

ACTION

APOLOGIES & WELCOME

Mr Nick Breeds, Mr Andrew Butler, Mr John Crookenden, Prof Sue Fuggle, Mr Paul Gibbs, Mr Charles Imber, Mr Edmund Jessop, Ms Sally Johnson, Mrs Judi Rhys, Dr Ken Simpson, Ms Susan Richards, Mr Anthony Snape, Mr Mick Stokes and Ms Lynne Vernon.

1 DECLARATIONS OF INTEREST IN RELATION TO AGENDA - LAG(18)1

1.1 There were no declarations of interest.

2 MINUTES OF THE MEETING HELD ON 22 NOVEMBER 2017 - LAG(M)(17)2

2.1 Accuracy

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

2.2 Action points – LAG(AP)(18)1

2.2.1 All action points have been completed. Those with a Verbal Report are listed with an update below.

AP 1- D Manas confirmed that vessels are to go with the liver following the split of a liver and a separate kidney/pancreas transplant leading to the liver not being split.

AP6 = J Asher reported that transplant centres are already using the suggested five different categories for recording the decline of organ offers and are happy. Work is still ongoing to reach consensus for category 3 entitled ' Organ unsuitable for named recipient'.

AP 8 – The service evaluation for Acute Alcoholic Hepatitis (AAH) is now formally closed.

2.3 Matters arising, not separately identified

2.3.1 <u>Consent</u>

C Callaghan invited feedback on the issue of whether patients should be informed of all offers relevant to them, including when their responsible clinician does not feel it is suitable for them. The clinical viewpoint was if treatment was felt to be suboptimal it did not make sense to inform the patient. A Taylor agreed that it was more important for patients to be given the surgeon's viewpoint. The viewpoint from S Matthew, as a Lay Member, was that a blanket ruling would undermine the confidence in surgeons.

LAG agreed that it was not appropriate to approve a blanket directive to inform all patients of all offers relevant to them. The issue has also been raised at PAG and KAG.

3 NATIONAL OFFERING SCHEME

3.1 ODT Hub Update

3.1.1 The National Liver Offering Scheme went live on the 24 March 2018. The new operating platform now enables organ offering to be undertaken by Hub Operations; 17 donors were offered on the night of the launch with 45 minutes to consider each offer. There has been an increase in the volume of donor activity since January of this year, though there is still ongoing work to resolve IT component issues.

ACTION

The NLOS monitoring committee held a telecon on 27 April 2018 to review the first month of the scheme. M Hudson presented a summary of the findings:

- one death on the waiting list reported so far.
- no change has been seen in patients listed with variant syndrome.
- there has been a significant increase in DBD donors which may have had an impact on DCD activity.
- currently looking at trying to get more information on livers retrieved and not transplanted.
- 254 (38%) offers (40 liver donors) were fast-track offers.
- paediatric transplants have increased slightly.
- there has been no evidence of an increase in CIT with a median of 8 hours and 40 minutes for the first month of NLOS.
- the scheme will be reviewed again in 3 months.

H Aldersley, recipient co-ordinator representative for adults, reported that overall the scheme had worked well.

N Heaton (King's College, London).

- seeing an increase in paediatric splitting; a welcome outcome.
- the refusal rate has gone up resulting in more work for the recipient co-ordinators i.e. possibly looking at 3 patients before an organ is accepted.
- a big problem has been whilst on call. There can be three offers of a DCD donor at various times with no transplant time given leading to situations where they all come through with the same start time. All activity for offers and transplants are gravitating to occurring after midnight which will not be sustainable for staff who will also be required to work during the day.

J Forsythe noted and welcomed the rise in organ donors with 1575 donors in the last year and over 5000 transplants; these are record figures. He reported that bringing in a new scheme in that period brought extra challenges and thanked all those who were involved in making it a success up to this point.

He stated that there are two issues that need to be addressed. The first is multiple offers which Hub Operations are currently trying to resolve. The second issue is 'unintended consequence' whereby the process of liver offering within the scheme i.e. specialist nurses, Hub Operations and the transplant centres have become disassociated compared to previously. Action is required to look at linking up the whole process of communication.

3.2 **Post implementation monitoring**

3.2.1 J O'Grady reported that the success of the scheme will be measured by metrics e.g. activity and organ utilisation dashboard, survival times, retrieval times to transplant and standard practice between centres, initially at 3 month intervals.

N Heaton recommended that the target should be organ utilisation; King's has experienced a decrease in organ utilisation.

An issue brought up was cardiothoracic teams being asked to get to retrieval quickly and ending up having to wait around e.g. before cross clamping,

ACTION

unavailability of an anaesthetist or waiting for the multi-visceral transplant. It was requested that this be resolved quickly. Refer to agenda item 10.3.

3.3 **Liver Patient Selection and Organ Allocation Policies - LAG(18) 2a & 2b**

3.3.1 The Liver Patient Selection Policy has been updated to include the National Liver Offering Scheme and has been agreed by the Senior Management Team. Centres can specify whether patients would consider a liver offer from a specific type of donor (e.g. DCD or split liver) as well as from a donor with a specific positive virology (e.g. HCV positive donor). The current default to both is "Yes" so that patients may receive all offers and would not be disadvantaged. However, it was agreed at ODT SMT in March 2018 that the default for donor virology should be null so that centres would have to specify an informed decision. This change in default values is subject to an IT change on both the registration and sequential data update forms. Centres have been contacted to clarify whether the “Yes” entered is a true Yes or a default value.

3.4 **Compliance with sequential data submission - LAG(18)3**

3.4.1 A revised version of the Sequential Data Collection (SDC) form was implemented on 14 December 2017. The report presented indicated that every transplant centre had returned at least 28 forms, 899 forms were received between 14 December 2017 and 24 April 2018 from the seven UK liver transplant centres. Of the 250 patients on the elective CLD/HCC transplant list on 24 April 2018, 40 (16%) had not had a SDC form within the last two months, no forms were received for 24 patients on the transplant list for more than one month and for 8 patients no SDC form had been received for 90 days.

Centres were reminded of the importance to return these forms to enable the matching run produced by ODT Hub Operations to accurately calculate patients' transplant benefit scores.

4 ADULT TO ADULT LIVE DONOR TRANSPLANT

4.4.1 D Manas informed members that the Strategy Programme has been produced and sent to NHS England. The British Liver Transplant Group (BLTG) will present the Strategy to the wider community.

There has been a modest increase in adult to adult live donor transplant numbers.

5 LIVER TRANSPLANT COMMISSIONING

5.1 NHS England

5.1.1 S Watson reported that liver transplant commissioning projections have been shared going up to 2022 with commissioning hubs though the projections do not take account of changes arising from the new National Liver Offering Scheme. Some variations have been made to the second year of the 17/19 contracts; data is currently being gathered on contracts from hubs.

The Commissioners hosted a strategy meeting with the transplant services and Professor Graham Foster, Chair of the HPB Clinical Reference Group, regarding the CRG's work on the development of HPB networks across England and how they should work with the liver transplant services.

ACTION

Transplant centres were asked to provide information on their hepatology networks to NHS England by the 12 June 2018. The recommendation was to use St James's University Hospital's strategy as the paradigm. Rebecca Jones to confirm if this is agreeable. **Centre Reps** **R Jones**

5.2 Peer Review

5.2.1 The national report has been drafted and is awaiting approval by the Department of Health. The report will be circulated in due course. To-date four centres have given their approval for their centre's information to be shared; Birmingham, Edinburgh, Leeds and London - Royal Free.

6 CLINICAL SERVICE EVALUATIONS

6.1 HCC Downstaging – LAG(18)4

6.1.1 As of 11 April 2018 (after 3 years) there were 15 down-staged HCC patients registered for transplantation, 13 of whom received a liver and 11 were known to be alive at their last follow up. Two of the 15 patients received organs through the new National Liver Offering Scheme.

The cancer model should be used to calculate the Transplant Benefit Score for new down-staged HCC patients and centres are asked to record cancer as one of the three indications at registration.

6.2 Hilar Cholangiocarcinoma (CCA) – LAG(18)5

6.2.1 N Heaton informed members of a meeting held in January. Cholangiocarcinoma UK are working with the British Association of the Study of the Liver (BASL) to define suitable patients for a possible Clinical Service Evaluation (CSE) for liver transplantation in cholangiocarcinoma. D Manas commented that PSC patients show the best outcome and have the greatest need. Prof Nigel Heaton agreed to chair a FTWU to develop the CSE.

E Hoti reported that they started their programme in Dublin in 2005. They had 38 patients with 27 receiving treatment. The results have been good with an 85% patient survival at 5 years. Two patients from the UK had been referred to Dublin for consideration for transplantation.

All centres agreed to support the development of the CSE. N Heaton to provide a proposal at the next meeting in November. **N Heaton**

7 LUNG AND LIVER SU LISTING – LAG(18)6

7.1 A proposal to automatically allocate the liver when a patient super-urgently listed for a lung or heart was allocated the organ was discussed. There was concern that this could divert the liver from a patient on the liver super-urgent list with more immediate clinic urgency. There was some support for the proposal if it involved a very small number of patients though M Hudson and A Gimson reported they have seen an increase in the number of these cases in recent years. N Heaton indicated his support for the lung and liver SU listing. It was agreed as a first step that SU lung patients would be offered the lung and the arrangement will be closely monitored.

8 HEPATITIS DAAs AND IMPACT ON DONATION

8.1 D Manas reported that wide-ranging consultation is still in progress. The potential donors involved are small, around 15 per year and about 70 organs.

ACTION

S Watson stated that NHS England will fund treatment for Hepatitis DAAs but they need to see details from the transplant community on patient selection to share with the Hep C network and understand if all centres or a selected number of centres are involved. This information needs to be looked at in parallel with the protocols for DAAs before being signed off.

Ahmed Elsharkawy will be invited to establish a group to develop operational policy across all organs.

9 CENTRALISED EXPLANT REVIEW, SU LISTING AND HCC

9.1 J O'Grady reported that this area of work is still in progress. An invitation to Chair a FTWU has been extended and a reply is awaited. It is hoped that a proposal to implement this important governance process will be tabled at the next LAG meeting in November.

10 GOVERNANCE ISSUES

10.1 Non-compliance with allocation

10.2.1 There have been no reports of non-compliance with allocation.

10.2.1 Detailed analysis of incidents for review – LAG(18)7

10.2.1 J Forsythe presented the report from John Dark and highlighted a number of incidents that have been reported.

He spoke about the length of the donation process and what measures had been enacted to attain improvement, which have not yet resulted in significant change.

Discussion took place about the reasons for the lengthening of the process and members of LAG offered opinions on the onward negative effects of this problem and ways in which improvement might be brought about.

N Heaton, in particular, highlighted the difficulty of performing complex transplant procedures in the middle of the night.

J Forsythe mentioned two meetings in the near future that will address resource issues. First, a Capacity and Demand Review for organ retrieval and a meeting of the clinical community to discuss options. Secondly a Sustainability Summit in June to highlight that, in the last year, there has been an 11% increase in workload with little or no increase in resource.

10.3 Incidents under review

10.3.1 J Forsythe outlined a case of potential non-compliance with the liver selection policy. This was also raised at the recent NLOS monitoring Committee and potential non-compliance will be monitored and dealt with more formally should more cases arise.

D Manas reported on two incidents at Birmingham since the last meeting. A meeting was held involving senior clinicians and managers from the Trust and NHS England. Another meeting was held in February looking at taking forward governance issues. A 'lessons learnt' document will be tabled on 2 May 2018 and will be circulated once agreement has been reached by all parties concerned.

ACTION

10.4 CUSUM

10.4.1 Report from recent CUSUM trigger and review

10.4.1.1 J Forsythe reported on an External Review Panel held in January this year led by P Gibbs regarding 9 cases leading to two triggers at the Leeds transplant centre. The report has been sent to all relevant parties.

R Jones informed members that areas have been identified for examination. A report has been issued last week with recommendations and this will be discussed as a team at their centre. Lessons to be learnt will be distilled and shared.

An additional two centres signalled against the centre-specific rate but not the national rate. As these were not against the national rate, it was agreed that the teams should examine carefully how these were triggered. The two incidents will be considered in the spirit of a 'near miss'.

10.4.2 Summary of CUSUM monitoring of outcomes following liver Transplantation – LAG(18)8

10.4.2.1 R Taylor presented a report indicating that over the last 12 months there have been three reported signals in liver transplantation. A formal external and internal review was held in January this year and a final report detailing actions to be taken is yet to be received.

Reporting on 90 days mortality rates following liver transplants under the new National Liver Offering Scheme will not be included in the CUSUMs until September 2018.

11 STATISTICS AND CLINICAL STUDIES (SCS) REPORT

11.1 Summary from Statistics and Clinical Studies – LAG(18)9

11.1.1 A summary of the key points from the report are:

- NHS England provides funding for two clinical fellows to support NHSBT's programme for audits and analyses. One is an ongoing post in cardiothoracic transplantation and the second post is shortly being advertised to work in abdominal organ transplantation.
- A NHSBT funded clinical fellow has recently started working on organ utilization.
- R Taylor raised an issue of patient identifiable information dating back to 1984 being requested by Public Health England. This is not something NHSBT have agreed to in the past. R Taylor to provide the full details to J Forsythe who will to take this forward within NHSBT. **R Taylor**

  Post Meeting Note:
  This will be raised at ODT Care in June 2018.
- Transplant centres are reminded of the importance of maintaining up to-date and accurate waiting lists via the NTxD ODT Patient List application as Statistics rely on the data to offer livers to transplant centres in the new NLOS. Transplant centres are also reminded to return post-transplant follow-up forms promptly in order for Statistics and Clinical Studies to produce accurate analyses.

ACTION

11.2 Transplant centre profiles – LAG(18)10

11.2.1 J Forsythe outlined to members the proposal to have a simple summary of information for each transplant centre, which may not be easy to locate on the website, with a small number of key metrics. None of the information presented is new and is already available. Transplant centre representatives and the liver patient charities were invited to give feedback before the proposal is circulated.

Transplant Centre Reps/ Patient Charities

12 RULES FOR SPLITTING IN THE NEW NATIONAL LIVER OFFERING SCHEME

12.1 M Attia raised the issue of rules for splitting in the new offering scheme. He outlined two paediatrics seen in Leeds weighing 40 and 42 kg respectively, both requiring a left lobe. It was agreed that the standing policy for splitting remains unchanged and any dispute should be resolved by the surgeons involved with the recipient of the left lobe being the index case.

13 PAEDIATRIC TRANSPLANTATION FROM SPLIT LIVER: TIMING AND UTILISATION

13.1 Refer to minute 12.1 above.

14 DCD LIVER SCREENING UPDATE – LAG(18)11

14.1 The DCD liver screening pilot was introduced on 1 December 2017 as part of the DCD donor assessment process to further improve donor screening and identify donors with a genuine potential to become an organ donor. In the first three months 1649 DCD assessment forms were submitted (approximately 80% of all DCDs) and 120 donors were screened for suitability for liver donation. Of these 120 donors, 100 were deemed unsuitable for liver donation. Of the 20 donors considered suitable following screening, one was transplanted. Further analysis is still required. The comment was made that more targeted information (e.g. blood group) would be beneficial. Members were happy to continue supporting this work.

15 HYPOTHERMIA IN DBD DONATION – LAG(18)12

15.1 J Forsythe presented a research study paper on behalf of C Watson which has shown positive results in terms of kidney function. The research team are keen to build on the study and further examine the temperature organs are held at before transplant. C Watson will come back with protocols at a later stage.

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

16.1 Report from the Multi-Visceral & Composite Tissue Advisory Group Meeting - 21 March 2018

16.1.1 P Friend informed members that there were no issues to report on directly affecting LAG.

16.2 **Paediatric status for intestinal patients with contracted abdominal cavity weighing more than 35 kg**

16.2.1 Refer to minute 16.3.

ACTION

16.3 **Simulation for adult patients weighing more than 35 kg with restricted abdominal cavity – LAG(18)13**

16.3.1 At the last LAG meeting P Gibbs reported that Addenbrooke's did not have a requirement for this. This was in fact incorrect, A Butler stated that they had two liver patients who have potentially been disadvantaged. The question is whether to approve paediatric status being given. P Friend asked members whether the option of a rectus sheath graft would be appropriate or to split a composite graft. He will raise this at the next MCTAG meeting. **P Friend**

17 ANY OTHER BUSINESS

17.1 J Asher informed members that the paper HTA form will be replaced by an electronic HTA form in July.

18 DATE OF NEXT MEETING:

Wednesday 21 November 2018, 12 Bloomsbury Square, London

19 FOR INFORMATION ONLY

The following papers were attached for information to members:

19.1 **Transplant activity report: April 2018 - LAG(18)14**

19.2 **Group 2 Transplants – LAG(18)15**

19.3 **Outcome of appeals – LAG(18)16**

19.4 **Activity and organ utilisation monitoring (dashboard) – LAG(18)17**

19.5 **Minutes of the Multi-Visceral & Composite Tissue Advisory Group meeting: 11 October 2017 - LAG(18)18**

19.6 **Minutes from the National Retrieval Group: 8 November 2017 - LAG(18)19**

19.7 **QUOD statistical reports - LAG(18)20**

New Appointments in NHSBT

Ms Ceri Rose has been appointed the interim Director of Marketing and Communications, replacing Léonie Austin leaving in May.