NHS BLOOD AND TRANSPLANT
ORGAN DONATION & TRANSPLANTATION DIRECTORATE

MINUTES OF THE THIRTY FOURTH MEETING OF THE LIVER ADVISORY GROUP HELD ON WEDNESDAY 21ST NOVEMBER 2018 AT 12 BLOOMSBURY SQUARE, LONDON, WC1A 2LP

PRESENT:

Prof John O'Grady	**Chairman**
Dr Douglas Thorburn	Incoming Chair, Royal Free Hospital and BLTG Rep
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
Mr Chris Callaghan	National Clinical Lead for Organ Utilisation (Abdominal)
Mr John Crookenden	Liver Patients' Transplant Consortium
Dr Ahmed Elsharkawy	Hepatologist, Queen Elizabeth Hospital, Birmingham, Birmingham
Prof John Forsythe	Associate Medical Director, NHSBT
Prof Peter Friend	Chair of Multi-Visceral & Composite Tissue Advisory Group & National Retrieval Rep, Oxford
Mr Tom Gallagher	Deputy for Dr Diarmaid Houlihan, St Vincent's University Hospital, Dublin
Mr Paul Gibbs	Surgeon, Addenbrooke's Hospital, Cambridge
Dr Tassos Grammaticopoulos	Physician, King's College Hospital, London
Prof Nigel Heaton	Surgeon, King's College Hospital, London
Dr Andrew Holt	Physician, Queen Elizabeth Hospital, Birmingham
Mr Emir Hoti	Surgeon, St Vincent's University Hospital, Dublin
Dr Mark Hudson	Physician, Freeman Hospital, Newcastle and Chair of the National Liver Offering Scheme Monitoring Committee
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
Dr Aileen Marshall	Hepatologist, Royal Free Hospital, London
Prof Paolo Muiesan	Surgeon, Queen Elizabeth Hospital, Birmingham
Ms Jacki Newby	Head of Referral and Offering, NHSBT
Mr James Powell	Surgeon, Royal Infirmary, Edinburgh
Dr Sanjay Rajwal	Paediatric Hepatologist, Leeds
Dr Ken Simpson	Physician, Royal Infirmary of Edinburgh
Ms Rhiannon Taylor	Statistics and Clinical Studies, NHSBT
Ms Lynne Vernon	Lay Member
Prof Stephen Wigmore	BTS Rep

IN ATTENDANCE:

Mrs Kamann Huang	Clinical & Support Services, ODT
Ms Caroline Robinson	Observer
Mrs Lizzie Abbot-Davies	Observer
Ms Lisa Mumford	Observer

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APOLOGIES & WELCOME

Mr Nick Breeds, Prof Sue Fuggle, Dr Diamaid Houlihan, Mr Ben Hume, Ms Vanessa Hebditch, Mr Charles Imber, Ms Sarah Matthew, Dr Indra van Mourik, Ms Susan Richards, Ms Laura Stamp, Mr Mick Stokes, Ms Alison Taylor and Ms S Watson.

E Jessop, NHS England, will be retiring at the end of the year. J Forsythe to write a letter thanking him for his support at the meetings. **J Forsythe**

J O'Grady welcomed Dr Andrew Holt replacing Dr James Ferguson.

Prof Paolo Muiesan will be on a year's sabbatical from January 2019. Mr John Isaac will be the Birmingham surgical representative in the interim.

CHANGE OF CHAIR

J Forsythe thanked J O'Grady for his 5 year term as Chair of the Liver Advisory Group and especially for his hard work in steering the National Liver Offering Scheme to its launch. This was echoed by the rest of the members and J Crookenden. Dr Douglas Thorburn will replace him from 1st December 2018.

1 DECLARATIONS OF INTEREST IN RELATION TO AGENDA - LAG(18)21

1.1 There were no declarations of interest.

2 MINUTES OF THE MEETING HELD ON 2 MAY 2018 - LAG(M)(18)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)(18)2**

2.2.1 **AP1** – Centre Representatives to provide more information on their hepatology networks to NHS England by 12 June 2018. This requirement has been superceded by a CRG initiative led by Prof G Foster.

2.3 Matters arising, not separately identified

2.3.1 There were no matters arising.

3 NATIONAL OFFERING SCHEME

3.1 **National Liver Offering Scheme (6 months data) - LAG(18)22**

3.1.1 A summary of results from the new National Liver Offering Scheme for DBD liver offers to named patients for the first six months since its introduction on 20 March 2018 is listed below:

- Overall registration activity:
  Data for the six month periods immediately before and after the introduction of NLOS showed an increase in both elective and super-urgent (SU) registrations post the introduction but there were no statistical significant differences between the two time periods.
- A higher proportion of new CLD and HCC registrations were transplanted in the first 6 months than patients listed prior to 20 March 2018. A higher

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proportion of variant syndrome patients on the list were transplanted compared with new registrations.

- Transplant list activity:
  512 adult elective patients joined the transplant list since implementation, 269 (53%) of the patients have received a transplant. The same corresponding transplant rate for patients active on the list on 19 March 2018 was 43%. There was an increase in transplantation for the first six months for all age groups except for the 40-49 year age group.

- Two clinical groups required additional insight – patients listed with HCC and elective re-transplantation. The analysis has been completed for HCC. The reasons for removal from the transplant list for 17 hepatocellular carcinoma patients were reviewed. J O'Grady noted that there were 4 patients who were on the transplant list for more than 1 year prior to being removed. Two no longer had an indication and one had improved. 13 of the 17 patients had all been on the transplant list for less than 110 days and most have evidence of tumour progression. The review concluded that the early removals reflected issues with patient selection rather than a problem with NLOS.

- The second group relates to patients listed for re-transplantation before the switch to NLOS and an in-depth analysis of this cohort is in progress.

- It was stressed that these are early data that are not generally powered to support firm conclusions and that there may be time-lag in the reporting of significant events.

3.2 **Feedback from the Monitoring Committee**

3.2.1 M Hudson informed members that since the NLOS the mortality rate has decreased to 4%. R Taylor to look at the mortality rate 12 months prior to the scheme but it is too early to comment on the survival rate from the point of listing. Patient registration has increased though the proportion of patients for HCC and CLD listed have remained the same. **R Taylor**

3.3 **Response to matters arising from 3.1 & 3.2**

3.3.1 Comments to paper LAG(18)22 – National Liver Offering Scheme – 6 month review.

- Data presented showed there was an increase in transplant activity for patients aged 60 years and over to 41%. It was commented that this could be a result of early re-grafts which would require a better understanding of the cause.

- J O'Grady raised the question of what should happen to a CLD patient who develops HCC while on the transplant list. It was agreed that the centre would contact NHSBT who would calculate the patient's TBS with and without HCC for a theoretical donor so that the centre involved could make the decision regarding which pathway would be the most appropriate for the individual patient. It was concluded that the NLOS is working well for chronic liver disease patients but more time is required to get more robust data.

- When the scheme went live, it was agreed that 10% of livers would be randomly allocated to variant syndrome patients. This was subsequently decreased to 8% because of a fall in the number of active registrants in

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that category. However, this trend subsequently reversed and a return to the 10% level was recommended and agreed.

- The Monitoring Committee and Core Group (CG) highlighted the need to understand why a higher than expected number of organs were being fast tracked than was anticipated. An in-depth analysis of organ flow through the system will be undertaken with particular emphasis on functionality and logistics as well as a review of the definition of the exit points from NLOS.

  P Gibbs raised a concern at Centre 3 regarding a late decline after retrieval. Several organs were on their way to the centre, following acceptance, then declined and fast tracked. It was commented that this could be a result of accepting too many livers at the time or down to a lack of theatre capacity. It was said that these livers were not marginal but were offered late. This will be investigated further. **R Taylor/ J Newby**

- S Wigmore brought up the fact that, even after an offer for a particular patient is accepted, further offers for that same patient are still made to the same centre. J Newby confirmed that this is happening for operational reasons that are being addressed with outcomes expected by March 2019. J Forsythe stated that the process be reviewed as it could lead to late declines. J O'Grady stated that, in the interim, there should be professional agreement that if a centre accepts a liver for a named patient it must stick by that decision even if a subsequent offer might be considered as preferable..

- V Aluvihare asked if there were centre data available for offer decline rates. This is currently not available but will be in the future.

3.4 **ODT Hub Update**

3.4.1 J Newby reported that there had been incidents regarding livers that did not meet the specified split criteria but individual centres believed that they could be split. J Newby stated that it was not clear to Hub Operations that if the liver is offered and split by the Centre, the right lobe should remain with the Centre. J Powell to formalise this with J Newby. **J Powell/ J Newby**

3.5 **DCD activity and inclusion in the National Liver Offering Scheme (NLOS) – LAG(19)23**

The offering scheme for donors after circulatory death (DCD) did not change with the transplant centre in whose donor zone the DCD appears receiving the first offer of the liver. J O'Grady stated that the issue of DCD organs being incorporated into the scheme was due for review after 6 months. Core Group looked at 3 key metrics and concluded that only 2 of these 3 satisfied the requirements to support a recommendation to proceed at this time. Core Group noted excellent 3-year survival rate with DCD organs and the ability to define a subgroup of DCD organs with the lowest level of risk. However, the issues influencing the uptake of organs in the NLOS need to be rectified before DCD organs are included.

P Gibbs stated that he would like machine perfusion to be developed in all transplant centres and then bring in DCD donors. In response to J Crookenden's question to how machine perfusion should be implemented, J Forsythe reported that a Preservation and Perfusion Strategy meeting had been held on 31 October 2018 to gain clinical research views and as a

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business model. We are currently awaiting economic analysis for the Business Case for NRP (normothermic regional perfusion) for liver usage across all centres from 1 April 2019. This will then go to the DoH for funding.

3.6 **Policy for prospective audit – LAG(18)24**

3.6.1 An audit triggered by a query from one centre identified that three livers in different centres were not used in the patients to whom they were allocated. This was not picked up by the NLOS. Further investigation showed that all three were very complex offering sequences and the decisions made were clinically appropriate and supported. The three original patients were not disadvantaged.

P Gibb questioned why the organs were not re-allocated back into NLOS and to understand why this was also not picked up by Hub Operations. J O'Grady highlighted that the NLOS needs to be transparent and forensically reliable and recommended a prospective policy of audit should be developed including agreed responses to any transgressions identified.

3.7 **Compliance with sequential data submission – LAG(18)25**

3.7.1 Overall, the return rate for Sequential Data Collection forms was reasonably good. However, centres were reminded that it is mandatory for them to submit their patient forms every 3 months so that the TBS (Transplant Benefit Score) accurately reflects the patient's condition. **All Transplant Centres**

4 ADULT TO ADULT LIVE DONOR TRANSPLANT

4.4.1 D Manas reported that the new NLOS has curtailed the original need for adult to adult live donor transplantation. Currently the waiting list is low and mortality is low. D Manas questioned whether this type of transplantation was still required. It was stated that certain patient groups would still benefit and it would be worth looking more carefully at cancer as a bigger indication. J O'Grady requested that the Working Group should reconvene early in 2019 to discuss the issue. **D Manas**

The topic of adult to adult live donor transplant was also raised at BLTG (British Liver Transplant Group) to gain feedback from patient groups and the clinical communities. NHS England reported that the HPB CRG were supportive of this proposal but there was no clinical consensus at BTLG for implementation of the live liver strategy as written.

5 LIVER TRANSPLANT COMMISSIONING

5.1 NHS England

5.1.1 A written update was submitted by NHS England saying "We are working with NHSBT and have planning figures for growth from NHSBT including impact of strategic change and Opt Out. NHS England is in discussion with the DHSC about the planning figures and likely costs to meet increased capacity both in respect of the Impact Assessment for Opt Out and the Long Term Plan."

J O'Grady informed members of the outcome of two meetings convened by Edmund Jessop looking at liver transplantation over the next 5 years. The conclusion was "there will not be a recommendation for new transplant centres". NHS England is very happy with the quality and service of liver transplantation provided. However, referral practices are inconsistent and sometimes illogical on a geographical basis. The meeting heard from

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Prof. Graham Foster that the expectation was for up to 30 centres to be recognised as suitable to manage complex hepatology and these will be required to have formal agreements for access to liver transplant services.

Peer Review
S Watson provided a written report stating that the national report was agreed and circulated by the Peer Review team.

6 CLINICAL SERVICE EVALUATIONS/PROPOSALS

6.1 HCC Downstaging – LAG(18)26

6.1.1 A service development evaluation to transplant HCC down-staged patients was introduced on 2nd March 2015 with transplant centres being responsible for ensuring patients meet the eligibility criteria.

Over the last three and a half years, 19 of the planned 4 patients have been listed. It was agreed that an analysis should be undertaken on the outcomes of these 19 patients. **R Taylor**

6.2 Cholangiocarcinoma (CCA) – LAG(18)27

6.2.1 N Heaton presented a joint proposal from Canada and Spain using liver transplantation for the treatment of early stages of intrahepatic cholangiocarcinoma in cirrhotics outlining eligibility criteria, exclusion criteria and the study results. Limitation of the study included the small number of participants and restriction to small tumours less than 2 cm. N Heaton believed it was a good study and expanding it into an international trial, to include the UK, would enable results to be achieved in a shorter time frame. Following discussion members supported participation in the trial. However, the scope for liver transplantation for cholangiocarcinoma was broader and it was agreed that a group would develop a proposal to address cases with the international trial that may benefit from liver transplantation.

N Heaton raised the issue regarding how patients included in this study would be offered livers through the National Liver Offering Scheme as it has been agreed that study participants would receive additional MELD "exception points" at centres currently employing MELD to allocate livers. This should be agreed at the next meeting. Raise as an agenda item. **K Huang**

P Gibbs extended the discussion to neuroendocrine tumours and the group agreed that it was timely to revisit this issue based on new information.
P Gibbs agreed to lead a FTWU on this topic.

6.3 Extracorporeal liver perfusion – LAG(18)28

6.3.1 D Manas outlined a letter from Newcastle upon Tyne requesting the support of LAG for their programme of extracorporeal liver perfusion to help patients with acute liver failure using organs that were allocated to research. The initiative was supported by P Friend and agreed by LAG. The proposal should be referred to RINTAG for comment. **D Manas/ H Crocombe**

7 SUPER-URGENT LISTING APPEALS MECHANISM – LAG(18)29

7.1 J O'Grady reported that the fast-track pathway was not performing as intended. The initial step of vetting by the Chair of LAG or Deputy was largely by-passed and a decision based on the number of responses received by 12 hours was not delivering robust consideration of the appeals. Some cases that did not meet any of the criteria for super-urgent listing has successfully

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negotiated the process. LAG approved reverting to the previous system which requires discussion with the Chair of LAG and at least 4 centres positively supporting the application.

8 USE OF HEPATITIS VIRAEMIC DONORS IN TRANSPLANTATION – LAG(18)30

8.1 A Elsharkawy, Chair of a Working Group, reported that SaBTO (The Advisory Committee on the Safety of Blood, Tissues and Organs) have recently changed their regulations to allow the use of a transplant from a HCV infected donor to a non-infected recipient. A policy development paper has also been published to BTS (British Transplant Society).

The main issue is funding of DAAs (direct acting antiviral agents). NHS Scotland and NHS Wales are willing to fund DAAs though NHS England has not yet finalised its position. J Forsythe commented that from NHSBT's perspective a common policy was highly desirable.

9 FTWU - CENTRALISED EXPLANT REVIEW, SU LISTING AND HCC

9.1 A FTWU was set up, chaired by Prof Stefan Hubscher and Dr Pauline Kane, to look at governance issues in relation to transplantation through the super-urgent allocation pathway and transplantation for HCC. The FTWU felt that their remit should be limited to HCC and advised that a second FTWU is convened to take forward the issue of independent review of explants from patients listed through the 'super-urgent' pathway.

10 GOVERNANCE ISSUES

10.1 Non-compliance with allocation

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

10.2 Detailed analysis of incidents for review – LAG(18)31

10.2.1 Incident, LAG INC 3131, was raised for discussion regarding histopathology not being available. John Dark is leading on a project to improve the access to histopathology and has a meeting with the Royal College of Pathologists shortly.

Incident LAG INC3351 was also raised regarding a centre registering a blood group A patient as requiring an identical blood group liver. The centre queried why the patient had not received an offer of a blood group O liver. It was agreed that the "identical" option should be removed from the super urgent registration form. **R Taylor**

10.3 CUSUM

10.3.1 Report on recent triggers

10.3.1.1 There has been one trigger reported since the last LAG meeting in May this year. The trigger has been reviewed with an External Panel and a Lessons Learnt document has been produced. K Huang to circulate the document. **K Huang**

A Lessons Learnt document has also been produced from a previous trigger. R Jones was requested to forward the document to K Huang for circulation asap. **R Jones/ K Huang**

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10.3.2 Summary of CUSUM monitoring of outcomes following liver Transplantation – LAG(18)32

10.3.2.1 Refer to item 10.3.1 above.

11 STATISTICS AND CLINICAL STUDIES (SCS) REPORT

11.1 Summary from Statistics and Clinical Studies – LAG(18)33

11.1.1 A paper outlining the work undertaken by SCS was presented. Two of the key points were:

- Maintaining accurate waiting lists. Centre weekly reports have been produced for active patients on the waiting list. Transplant Centres were reminded of the importance of maintaining up-to-date and accurate liver waiting lists via the NTxD ODT Patient List Application to enable offers of livers to be made in the new NLOS and to provide for reporting in the Annual Report.
- Donor risk index. N Heaton raised a concern regarding whether the information listed was from an academic background or a clinical background. This work was undertaken by D Collett with C Watson and P Friend on the Committee. It was agreed that the DRI should not be used in clinical practice without agreement.

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

12.1 Report from the Multi-Visceral & Composite Tissue Advisory Group Meeting - 24 October 2018

12.1.1 There were no major issues to be raised apart from one raised by A Butler, Addenbrooke's, regarding a change in Intestinal Policy to paediatric status for intestinal patients with contracted abdominal cavity weighing more than 35 kg and to ascertain any potential disadvantages on liver patients. L Sharkey reported that Addenbrooke's still have a highly sensitised patient with a small donor cavity on their waiting list after 3 years. MCTAG reported that owing to a tiny number, 1 or 2 patients, that are affected, it agreed that similar cases in the future will be dealt with on a case by case basis rather than make a special case to LAG to change the rules. This was approved by LAG.

13 ANY OTHER BUSINESS

13.1 **Organ Quality Forms Update – LAG(18)42**

Work is being undertaken for the development of electronic Organ Quality Forms to replace HTA Form A and B. However there has been a delay in the development of Form A which is currently scheduled to start in April 2019. The provisional eForm B is on track and is expected to rollout in December 2018 starting with the pancreas transplant centres.

13.2 **Recording reasons for liver non-use - LAG(18)43**

J Asher presented an updated list, since November 2017, of reasons for the decline of liver offers. The additional items were highlighted in italics.

V Aluvihare questioned whether there was screening for Tjer HTA B8. J Forsythe reported that work has been undertaken to review this with a paper submitted to the Governance Committee. NHSBT have written to

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J Neuberger, Chair of SaBTO, to make changes. A Working Group will also be set up.

14 Date of next meetings:

- Wednesday 8th May 2019, 12 Bloomsbury Square, London.
- Wednesday 20th November 2019, 12 Bloomsbury Square, London.

15 FOR INFORMATION ONLY

The following papers were attached for information to members:

15.1 **Transplant activity report: October 2018 - LAG(18)35**

15.2 **Group 2 Transplants – LAG(18)36**

15.3 **Outcome of appeals – LAG(18)37**

15.4 **Activity and organ utilisation monitoring (dashboard) – LAG(18)38**

15.5 **Consent for the use patient information and General Data Protection Regulations (GDPR) - LAG(18)38**

15.6 **Minutes of the Multi-Visceral & Composite Tissue Advisory Group meeting: 21 March 2018 - LAG(18)39**

15.7 **Minutes from the National Retrieval Group: 3 October 2018 - LAG(18)40**

15.8 **QUOD statistical reports – November 2018 - LAG(18)41**

New Appointments

Ms Betsy Bassis has been appointed the new Chief Executive for NHSBT, replacing Ms Sally Johnson, in the New Year.

Organ Donation & Transplantation Directorate **November 2018**

Administrative Lead: Kamann Huang