NHS BLOOD AND TRANSPLANT
ORGAN AND TISSUE DONATION & TRANSPLANTATION DIRECTORATE

MINUTES OF THE FORTIETH MEETING OF THE LIVER ADVISORY GROUP HELD ON WEDNESDAY 19 MAY 2021 AT 11 AM VIA MS TEAMS VIDEO CONFERENCING

PRESENT:

Prof Douglas Thorburn	**Chairman**
Prof John Forsythe	Medical Director, OTDT for NHSBT
Mr John Isaac	Deputy Chair, Surgeon, Queen Elizabeth Hospital, Birmingham
Ms Anya Adair	Surgeon, Royal Infirmary of Edinburgh
Dr Michael Allison	Hepatologist, Addenbrooke's Hospital
Dr Varuna Aluvihare	Physician, King's College Hospital
Mr Mark Aldersley	Physician Co-ordinator Representative
Ms Ayesha Ali	NHS England Rep
Mr John Asher	Medical Health Informatics Lead
Mr Magdy Attia	Surgeon, Leeds Teaching Hospital
Dr Will Bernal	Consultant, King's College Hospital
Ms Hannah Barlett-Syree	Organ Donation Rep, Deputy for Ms Becky Clarke
Mr Andrew Butler	Chair of Multi-Visceral & Composite Tissue Advisory Group
Mr Ian Currie	National Clinical Lead for Organ Retrieval
Dr Ahmed Elsharkawy	Hepatologist, University Hospital of Birmingham
Mr Paul Gibbs	Surgeon, Addenbrooke's Hospital, Cambridge
Dr Tassos Grammatikopoulos	Physician, King's College Hospital, London
Ms Pam Healy	Chief Executive, British Liver Trust
Dr Andrew Holt	Physician, Queen Elizabeth Hospital, Birmingham
Dr Mark Hudson	Chair of the National Liver Offering Scheme Monitoring Committee
Ms Rachel Johnson	Head of Statistics and Clinical Research
Prof Derek Manas	National Clinical Lead for Governance, NHSBT
Dr Aileen Marshall	Hepatologist, Royal Free Hospital, London
Dr Steven Masson	Hepatologist, The Freeman Hospital, Newcastle upon Tyne
Mrs Sarah Matthew	Lay Member
Prof Jörg-Matthias Pollok	Surgeon, Royal Free Hospital
Mr Krishna Menon	Surgeon, King's College Hospital
Ms Lisa Mumford	Statistics and Clinical Research, NHSBT
Mr Thamara Perera	Surgeon, Birmingham Children's Hospital
Mr Raj Prasad	Surgeon, St James's Hospital
Dr Sanjay Rajwal	Paediatric Hepatologist, Leeds
Dr Ian Rowe	Hepatologist, University of Leeds
Dr Tracey Rees	Scientific Officer
Mr Peter Robinson-Smith	Recipient Co-ordinator Representative
Mr Gourab Sen	Surgeon, The Freeman Hospital, Newcastle upon Tyne, Deputy for Prof Steven White
Dr Tahir Shah	Hepatologist, University Hospital Birmingham
Dr Ken Simpson	Physician, Royal Infirmary of Edinburgh
Ms Rhiannon Taylor	Statistics and Clinical Research, NHSBT
Ms Alison Taylor	Liver Transplant Consortium Rep
Ms Sadie Von Joel	Recipient Co-Ordinator
Ms Sarah Watson	NHS England Rep
Ms Julie Whitney	Head of Referral and Offering, NHSBT

IN ATTENDANCE:

Mrs Kamann Huang	Clinical & Support Services, ODT

Ms Jenni Banks (Observer)
Mr Lewis Downward (Observer)
Ms Sinead O'Brien (Observer)

ACTION

APOLOGIES & WELCOME

Apologies:
Mr Chris Callaghan, Ms Becky Clarke, Mr Emir Hoti, Ms Katherine Quist, Ms Lynne Vernon and Prof Steven White

1 DECLARATIONS OF INTEREST IN RELATION TO AGENDA - LAG(20)29

1.1 There were no declarations of interest.

2 MINUTES OF THE MEETING HELD ON 18 NOVEMBER 2020 - LAG(M)(20)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)(21)1**

2.2.1 All Action points are referred to as agenda items with the exception of the following two:

Protocol and dataset for machine perfusion
During the 6 months pilot, there have been a few occasions of a recipient centre B travelling to collect the liver from recipient centre A, taking with them their own machine and a set of disposables. There still appears to be a lack of clarity regarding the protocol. K Huang will raise this as an agenda item at LAG Core Group. **K Huang**

Summary points of the 30 month report: 20 March 2018 - 19 September 2020
Details of the 167 patients removed and their survival from the point of registration to extend to all patients removed since March 2018 will be picked up through the NLOS monitoring group.

2.3 Matters arising, not separately identified

There were no matters arising.

3 MEDICAL DIRECTOR'S UPDATE

3.1 **Organ donation and transplantation after COVID 19 surge and VITT**

There has been a downturn in donation during the COVID-19 surges last October and during January/February this year. However, a huge effort has been made to keep transplantation functioning by centres leading to a relatively small reduction of 20% in terms of overall transplant numbers in the last financial year. This is a testament to the amount of hard work that has taken place in donation and ICU's to allow donation to take place during very difficult times, for retrieval teams travelling across the country and transplant teams working tirelessly in their units. This work has been in collaboration with NHS England to enable the movement of patients between centres and we are now largely back to normal in terms of transplantation and centres being open. JF expressed his gratitude to all the people involved during this time.

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Further points of discussion:

- It was acknowledged that Birmingham are still operating below their normal levels in CT transplantation. Continued communication between J Forsythe and the MD of Birmingham was welcomed.
- The recognition of the involvement of lay and patient representatives in meetings e.g. COVID-19 meetings allowed an efficient two-way information channel to be circulated to patient groups as well as timely feedback to NHSBT.
- NHSBT were closely involved with the information produced by the British Haematology Urgent Group regarding the new syndrome associated with at least one of the COVID-19 vaccines. Guidance is being followed for organ donor usage, transmission and follow up of recipients. A paper was submitted to Lancet regarding the cases of donors and recipients but was turned down. The paper will be submitted elsewhere. To-date, there have been seven liver transplants from 6 VITT donors. Two have been retransplanted and five grafts are functioning well.
- NHS England are supporting the initiative for all six English liver transplant centres to maintain operating during any future surges, with a fall back of three protected centres. In the case of paediatric centres, two of the centres will be protected out of the three.
- Feedback from the BAME community on the NHSBT website has been very useful in promoting organ donation.
- It is hoped that the 10 year NHSBT donation, transplantation, organ utilisation and resourcing strategy will be launched in a couple of weeks.

NHSBT OTDT bulletins are circulated widely and to patient groups. If this is required to be circulated wider, please let NHSBT know.

3.2 **Liver utilisation report 4 February 2020 to 10 May 2021 (for noting) – LAG(21)2**

Item 3.2 LAG(21)2 Liver utilisation up to

4 UPDATE ON THE NATIONAL OFFERING SCHEME

4.1 Compliance with sequential data submission (SDC) - LAG(21)3

4.1.1 NHSBT have received 7700 SDC forms between 14 December 2017 and 28 April 2021 across all seven UK liver transplant centres. However, it was highlighted that of the 426 patients on the elective CLD/HCC transplant list on 28 April 2021, only 24% (101) SDC forms had been returned over the last two months and no SDC forms have been returned for 66 patients who were on the transplant list for more than one month.

Centres were reminded to return their forms regularly so that the TBS score accurately reflects the patient's condition.

4.2 National Liver Offering Scheme (36 months data) and summary feedback from NLOS - LAG(21)4

4.2.1 Points raised from the report:

- Fig 13: HCC offers have gone up significantly. This could possibly be a result of more clinically urgent patients being registered and HU patients being prioritised during the first wave of COVID 19 with more patients

receiving DBD organs compared to previous years. It would be interesting to see what criteria is used for identifying CU patients by centres as CU patients at Birmingham are not identified by NLOS as urgent.

- Table 7: For the 24 months before and after NLOS, mortality is lower post NLOS. Overall mortality has increased to 9% from 7%. Further analysis will be undertaken to look at this.
- There has been an increase in DCD's not retrieved with fewer DCD transplants and an increase in DBD's not proceeding to transplant. It is unclear whether this has been a result of COVID-19. The waiting list will be monitored to examine any future changes.
- Overall, there was no significant difference for DBD and DCD transplant survival at 90 days or at one year for the two time periods.
- More CLD and HCC downstaging patients continue to be transplanted in the 6 months period post.

Overall, the trends are consistent with previous reports and it was good to see an increase in transplants for HCC patients.

4.3 Updating the TBS parameter estimates - LAG(21)5a & 5b

Work on the TBS parameters has been going on for 18 months now. The FTWU has recommended Simulation 12 as providing the best overall estimated results using the metrics of estimated deaths, allocation to HCC patients and estimated patient life-years. It was highlighted that examination of a further refinement will be undertaken and details will be circulated. The recommendation was approved by LAG members.

An existing on-line calculator will be updated by I Rowe and circulated to all centres to enable centres to examine the impact of change for patients currently registered. It will be up to individual centres to familiarise themselves with the updated TBS.

5 UPDATE FROM FTWUs

5.1 ACLF - LAG(21)6a, 6b & 6c

5.1.1 This process is for patients with cirrhotic chronic liver disease who are not eligible for the Super-Urgent (SU) tier and is not a route for liver transplantation for Acute Alcoholic Hepatitis. It was stated that futility issues e.g. possible changes to the patient during the time lag from registration to organ offering has been taken into consideration and possible unintended consequences for some groups of patients e.g. multi-visceral transplant has also been considered, though not large numbers are expected. Registration will be undertaken during day-time working hours. Potential candidates will be selected by the individual transplantation centre after a local multi-disciplinary team review and approval for listing is required by either the Chair or deputy Chair of LAG in addition to W Bernal in his role as FTWU lead. Transplant centres should note additional data is required for ACLF patients.

W Bernal will provide an updated paper for circulation.

5.2 Minimal listing criteria for HCC– LAG(21)7 – Deferred

5.2.1 Work remains on-going and it is anticipated a paper will be presented at the next LAG meeting in November.

5.3 Hepatopulmonary syndrome patients

5.3.1 The FTWU work chaired by Jo Leithead defined the new selection criteria for HPS patients to be listed as chronic liver disease (CLD) with UKELD ≥ 49 or variant syndrome. Those with preserved liver synthetic function (UKELD <49)

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should only be listed if the the HPS is severe (PaO2 <8 kPa). All patients will require sequential updates to monitor their progress while waiting and this will need to be added to the data collection forms in future. Additional parameters of interest.e.g. frailty and quality of life needs to be reflected on the data collection forms in the future. Volunteers are required to examine the data currently collected on the UKTR and recommend any changes. A Data FTWU will be established and any interested members are to email D Thorburn direct or names will be recommended at the LAG Core Group meeting.

LAG Members

The very severe HSP patients are not served well by the variant syndrome (VS) method of prioritisation. The approximate waiting time on the VS waiting list is two years. To overcome this, the suggestion was made to allocate a fixed number of days waiting at the point of listing. Further analysis is required for this and to understand the number of patients that will be affected to ensure an adequate number of donors going down this pathway. The current offering is 1 in 10 donors going to the VS offering list. This will be picked up through LAG Core Group.

LAG Core Group

5.4 HCV positive transplants into HCV negative recipients – LAG(21)8a & 8b

Six of the seven liver centres have signed up and King's are in the process of doing so. Only 7 out of the 21 kidney centres have signed up. Advice and resources are being provided to help encourage the sign up of centres. It was commented that the low rate of sign up could be in part due to COVID, lack of a champion and the extent of governance that is required whilst a cross centre arrangement may be easier at some centres than others; four of the kidney centres signed up are linked to the liver centres.

The rate of consent for accepting HCV positive donors for HCV negative recipients for individual centres is not currently known, though it has seen to be high in some centres and low in others. Hubs are therefore not ready to make a change in offering yet.

It was stated that there is also currently no data on the types of organs used. Work is being undertaken looking at Hep C positive donation but the majority of organs declined were due to virology and not due to the quality of the organs.

5.5 Liver Offering

5.5.1 Neuroendocrine Tumours (NET) – LAG(21)9

5.5.1.1 As raised at the last meeting, having a national MDT will serve as a quality governance group as well as informing the wider community. Agreement needs to be reached on liver offering for these recipients to be transplanted within six months and for a SOP and patient pathway to be drawn up. It is hoped the programme will go live by the next LAG meeting in November.

5.5.2 Cholangiocarcinoma – LAG(21)10

5.5.2.1 The work undertaken by the FTWU chaired by N Heaton is now closed. An implementation group to start the programme will be led by R Prasad. The aim is to have all the work required completed by LAG in November for a final presentation to be made. It is anticipated the programme will go live by next year.

The discussion with Maria Hawkins looking at neo-adjuvant proton beam therapy will also need to be finalised and to establish whether this will fall into research or routine clinical care.

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5.5.3 DCD liver/kidney offering – LAG(21)11

5.5.3.1 Both the Chairs of KAG and LAG have agreed that DCD kidneys for liver/kidney patients will follow a similar process as for DBD kidneys. When a DCD offer is made to a zonal/paired linked centre(s), the kidney will be held back, subject to there not being any high priority patients in the new Kidney Offering Scheme. The centre can accept both the kidney and liver. If declined by both the zonal and linked centre(s) the kidney will return to the KOS and the liver is fast tracked without the kidney. This recommendation was approved by LAG and will be fed back to KAG. **J Whitney**

This should not cause any problems in the delay of kidney offering and the offering outcome and reasons declined will be reviewed on a regular basis (first 5, 10 and 20 occasions when organs are accepted). **J Whitney/ Statistics and Clinical Research**

It was reported that the use of NRP for DCD simultaneous liver and kidneys have a better tolerance of ischaemia and have given very good transplant outcomes and consideration of acceptance of these organs will be up to individual centres.

6 LIVER TRANSPLANT COMMISSIONING

6.1 **NHS England – AME Update**

Fiona Marley, Head of Highly Specialised Commissioning, NHS England, has responded to the proposals put forward by the liver community to the Rare Diseases Advisory Group (RDAG) regarding additional adult liver transplant providers in the South West and the North West of the country (Plymouth and Aintree). (NHS England letter circulated to LAG members on 18th May).

RDAG recommended that NHS England should undertake a national review of adult liver services looking at factors such as the existing expertise and transplant numbers, whether current transplant centres can meet the expected increase in transplant numbers following the passing of the Opt-Out legislation, technologies that can increase organ utilisation and secondary/tertiary hepatology provision. The earliest the review could take place would be 2022/23. Commisioners from Scotland, Ireland and Wales have been made aware of the review. The HSCT will be working with stakeholders to take forward the areas of work set out by RDAG.

In summary, the agreement is that the proposal for an additional provider of adult liver transplant services in the South West and North West of the country will not be taken forward at this current time.

7 GOVERNANCE ISSUES

7.1 Non-compliance with allocation

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

7.2 Governance

7.2.1 **Governance Report – LAG(21)12**

7.2.1.1 Points raised:

- The number of organs not used have increased.
- An incidence was raised regarding a non-UK citizen having a SU liver transplant by using another person's ID. It was stated that emergency transplantation cannot be withheld (even if the patient is not elgible for NHS care) if it is life-saving and it is unlawful under the Human Rights Act of

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1988. However, it is down to the clinician to decide whether treatment is classed as an emergency.
- A non-EU and non-UK citizen transplant document is being drawn up. D Manas will share the document as soon as it is available.
- Work is being undertaken to standardise donor imaging to enable quicker and easier understanding of information.
- Centres are asked to comply with feedback regarding donor disease transmission.

7.3 CUSUM

7.3.1 **Summary of CUSUM monitoring of outcomes following liver Transplantation – LAG(21)13**

All previous CUSUMs are closed.

7.3.2 Report on recent triggers (shared learning)

7.3.2.1 Over the last six months, there has been one signal against the centre's own specific rate but not against the national rate so no formal investigation is required.

All learning has been shared.

8 STATISTICS AND CLINICAL RESEARCH REPORT

8.1 Summary from Statistics and Clinical Research – LAG(21)14

8.1.1 Statistics and Clinical Studies merged in March 2021 with the NHSBT Research and Development office and the Systematic Review Initiative (SRI) and will now be known as Statistics and Clinical Research.
There are currently three clinical fellows working with the statistics team across transplantation in abdominal organ utilisation, malignancy and cardiothoracic.

8.2 Winton centre analysis – LAG(21)15

8.2.1 NHSBT have been working with the Winton Centre for Risk and Evidence Communication, at the University of Cambridge, to design an online risk communication tool to aid clinicians and patients in decision-making at different points in the transplantation process.

The first online tool will be for lungs. This will be released to the lung clinicians for feedback to NHSBT. The tool will be reflecting a specific time point so will always be on slightly older data and the parameter estimates will be updated on a yearly basis. Patients will be able to use the tool to look at different centres but it was highlighted that this is not to be used as a comparison site tool and the predictions need to be discussed with the patient's own clinician for a comprehensive evaluation. The tool was well received by the LPTC representative. It is hoped the lung tool will go live by September this year. The tool will then be created for liver, kidney and the heart by the end of the year or next January.

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

9.1 Report from the Multi-Visceral & Composite Tissue Advisory Group Meeting - 17 March 2021

9.1.1 Two main points were raised by MCTAG. One was the long waiting time for paediatrics waiting for a small bowel transplant. King's have patients waiting up to three years for grafts and have been imaginative in using cut down grafts from larger livers but it remains a significant problem. M&F Health is

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working with MCTAG to raise public awareness of small bowel transplantation for patients with intestinal failure using various initiatives such as a virtual workshop, a radio day and social media campaigns.

The second point is the use of small donor organs in MV recipients and for hepatoblastoma patients is currently a conflict. A paediatric hepatoblastoma patient requiring a liver will take priority over the MV patient who has been waiting much longer. These are small numbers and the vast majority of hepatoblastoma paediatric patients have received split livers. There is ongoing discussion between paediatric centres and the issue will be raised as an agenda item at the LAG Core Group and at a Paediatric meeting. However, it was noted that an IT change may be required **K Huang**

There is currently no CUSUM for this type of transplant so a Peer Review is being set up for monitoring outcomes similar to other organ groups.

10 ANY OTHER BUSINESS

10.1 **Liver Transplantation for colectoral liver metastases – LAG(21)16**

10.1.1 This topic has been raised before and was previously recommended to go down the Research Study.

There is now increasing outcomes data now for the work to progress now to a service evaluation. Following discussion LAG approved the establishment of an FTWU to make recommendations on developing a pilot programme at LAG in Nov 2021.

10.2 **UK Liver Alliance update**

10.2.1 The UK liver Alliance has been established to raise the profile of liver disease and tackle significant gaps in care for patients within the UK currently. It is represented across all four nations and by members of the Liver Trust, BASL, hepatology representatives and A Taylor, Graham Foster and D Thorburn from LAG.

The organisation is looking to come up with solutions to try and address the deficiencies nationally with the burden of liver disease and mortality.

A new Steering Group has been set up and will hold six meetings annually, with two meetings held to-date. One workstream is to unify the patient voice and this will necessitate establishing a patient forum similar to the LPTC. It is too early to communicate anything at the moment.

10.3 **Liver imaging proposal – LAG(21)25a & 25b**

10.3.1 The proposal from Chris Callaghan is to adopt a standard method of imaging for livers as undertaken by kidneys e.g. attach photos of the kidney at the kidney offering stage to the recipient centres. The pictures could also be stored in a repository to provide shared routine learning for e.g. using machine technology. This was approved by LAG and Chris Callaghan will take forward.

11 Date of next meetings:

- Wednesday 24 November 2021 -

12 FOR INFORMATION ONLY

The following papers were attached for information to members:

ACTION

12.1 Transplant activity report: April 2021 - **LAG(21)17**
12.2 Group 2 Transplants - **LAG(21)18**
12.3 HCC Downstaging **- LAG(21)19** Aileen will put together an early report.
12.4 Outcome of appeals - **LAG(21)20**
15.5 Activity and organ utilisation monitoring (dashboard) **- LAG(21)21**
12.6 COVID-19 Clinical Advice
https://www.odt.nhs.uk/covid-19-advice-for-clinicians/#vaccine
12.7 Minutes of the Multi-Visceral & Composite Tissue Advisory Group meeting: 21 October 2020 - **LAG(21)22**
12.8 Minutes from the Retrieval Advisory Group: 29 September 2020 **- LAG(21)23**
12.9 QUOD statistical reports for March 2021 **- LAG(21)24**
12.10 Organ Donation and Transplantation from Patients with Vaccine Induced Thrombosis and Thrombocytopenia (VITT)
https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/22975/inf1569.pdf

Administrative Lead: Kamann Huang **May 2021**