

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

**MINUTES OF THE THIRTY NINETH MEETING OF THE  
LIVER ADVISORY GROUP**

**HELD ON WEDNESDAY 18 NOVEMBER 2020 AT 11 AM VIA MS TEAMS VIDEO CONFERENCING**

**PRESENT:**

Prof Douglas Thorburn	<b>Chairman</b>
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
Mr John Asher	Medical Health Informatics Lead, NHSBT
Dr Varuna Aluvihare	Physician, King's College Hospital
Mr Mark Aldersley	Physician Co-ordinator Representative
Mr Magdy Attia	Surgeon, St James's University Hospital, Leeds
Mr Andrew Butler	Chair of Multi-Visceral & Composite Tissue Advisory Group
Mr John Crookenden	Liver Patients' Transplant Consortium
Prof John Dark	Newcastle University
Dr Ahmed Elsharkawy	University 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
Dr Joanna Leithead	Physician, Addenbrooke's Hospital, Cambridge
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
Ms Nicky Matthews	Organ Donation Rep, Deputising for Ms Becky Clarke
Mrs Sarah Matthew	Lay Member
Prof Jörg-Matthias Pollok	Surgeon, Royal Free Hospital
Mr Krishna Menon	Surgeon, King's College Hospital
Mr Tamara Perera	Surgeon, Birmingham Children's Hospital
Mr Raj Prasad	Surgeon, St James's Hospital
Ms Katherine Quist	Recipient Co-ordinator, Royal Free
Dr Sanjay Rajwal	Paediatric Hepatologist, Leeds
Mr Peter Robinson-Smith	Recipient Co-ordinator Representative
Dr Ken Simpson	Physician, Royal Infirmary of Edinburgh
Ms Rhiannon Taylor	Statistics and Clinical Studies, NHSBT
Ms Sadie Von Joel	Recipient Co-ordinator
Ms Sarah Watson	NHS England Rep
Dr Steven White	Surgeon, The Freeman Hospital, Newcastle upon Tyne
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)

**APOLOGIES & WELCOME**Welcome:

- Dr Raj Prasad replaces Magdy Attia (Surgeon - Adults & Paediatrics, Leeds).
- Mr Andrew Butler replaces Peter Friend as new Chair of MCTAG.
- Dr Steven Masson (Hepatologist - Newcastle upon Tyne)
- Dr Michael Allison replaces Joanna Leithead (Hepatologist - Cambridge).
- Ms Sadie Von Joel, covering for Laura Stamp (Lead Nurse - Recipient Co-Ordinator) on maternity leave for a year from September 2020).

Apologies:

Mr Chris Callaghan, Ms Becky Clarke, Mr Emir Hoti, Dr Diarmaid Houlihan, Dr Tracey Rees, Ms Alison Taylor and Ms Lynne Vernon.

**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 20 MAY 2020 - LAG(M)(20)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)(20)1**

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

AP1- ODT Hub update – maximum opportunity to be given for the liver to meet organ utilisation

If the NORS retrieving surgeon deems the retrieved organ unsuitable, this will be discussed with the accepting surgeon and the organ will not be offered on by the SNODs.

AP3 - DCD Utilisation

The work looking at DCD utilisation and livers turned down will be undertaken via a prospective audit, as part of the clinical lead for organ utilisation programme. Action Closed.

AP7 - Protocol and dataset for machine perfusion

D Manas reported that it has been agreed that the recipient centre B would travel to collect the liver from recipient centre A, taking with them their own machine and a set of disposables. The machine will need a special device, an inverter, to ensure the machine is properly charged. This proposal was planned as a pilot for 6 months. As there have been no instances, the plan is to run the pilot for another 6 months. A standard data set has been defined to accompany any liver based on the initial NMP parameters. The cost in travel incurred will be borne by the centre and not NHSBT. Feedback from the extended 6 month's pilot to be given at the next LAG meeting in May.

**D Manas**AP8 – Cholangiocarcinoma

Maria Hawkins believes that using proton treatment, available only to certain centres, for cholangiocarcinoma will not be a problem. Closed.

AP10 – Report from MCTAG – 11 March 2020Conflicting demand for organs from small DBD donors for liver patients with hepatoblastoma versus small paediatric patients requiring multi-visceral (MV) transplants (potentially with hepatoblastoma, too)

Paediatric patients requiring MV transplants require appropriately sized organs (donor max weight 10kg), so there is a conflict between paediatric MV patients and liver only hepatoblastoma patients on the waiting list. This is because the latter receive priority over any elective intestinal patient. The final decision will rest with the paediatric centre. Liver hepatoblastoma patients can receive split livers, whereas MV patients cannot. MCTAG questioned whether, therefore, the priority of liver hepatoblastoma over paediatric MV patients should be reviewed. Encouraging a conversation and seeking an agreement is in the intestinal paediatric centres' hands. Closed.

Abdominal wall fascia for abdominal wall reconstruction

The HTA regard fascia as a tissue and, not an organ, thereby requiring different regulations for testing, storage and utilisation. There is no substantial HTA concern regarding the use of fascia in patients who are undergoing transplantation of a solid organ from the same donor, but there is concern if the fascia is to be used in a patient not undergoing transplantation of a solid organ. In particular, this raised issues of traceability of the fascia; if this issue is resolved then there is no underlying problem with the use of the fascia as a third-party graft.

The issue of retrieval was discussed: at present, only Cambridge, King's College Hospital and the Royal Free Hospital retrieval teams are trained to retrieve isolated abdominal fascia. There are plans for a training video.

There have been discussions with the NHSBT Tissue Bank in Liverpool regarding the storage of fascia.

It has been proposed that the retrieval of fascia will be carried out in a pilot region (East Anglia) first and, if successful, extended to the rest of the UK. A Butler and V Gauden to put together the plan and A Butler to circulate this when finalised. Closed.

**2.3 Matters arising, not separately identified**

There were no matters arising.

**3 Update on Opt-Out and Organ Donation****3.1**

The Organ Opt-Out legislation has been in force in England since May 2020 with a planned implementation date of March 2021 for Scotland. An increase in consent for donation has been seen over the last few months, although it is difficult to know if this is a result of the legislation or to the current public empathy towards the NHS due to COVID-19. To-date 120 donor families have given consent under the deemed legislation section and we are about to report on the 6 month's data following the legislation change.

Weekly Clinical Team meetings are held, in conjunction with separate weekly meetings with all the commissioners for transplantation across the UK, in order to monitor the pandemic as well as to continue to manage the second wave. The retrieval and transplant teams' network within the UK are excellent with a good two-way communication with NHSBT.

**3.2 Organ donation and transplantation after COVID-19 surge**

It was acknowledged that there have been difficulties within some centres to access ICU and theatre during the second COVID-19 surge. J Forsythe paid tribute to the collaborative work between transplant centres to try and make

## ACTION

the best use of resources where possible, which has pulled the community together. A letter from the OTDT MD has been sent out to the Medical Directors for circulation within the transplant centres providing guidance in terms of competing priorities.

Funding has been secured for an initiative on organ utilisation. The time-line objective was to have a Clinical Lead for Utilisation (CLU) in place for every transplant centre (54 CL's in total) by the end of October. With the exception of a couple of transplant centres we were able to have a CL in every centre which has been a tremendous achievement. The funding will be until the end of the financial year. If the project provides positive results, it is hoped the project will become more long term.

Two surveys have been sent out regarding utilisation problems in centres. Obtaining a good thumbprint and over-arching themes to be addressed would be a good outcome. It is hoped the project will highlight barriers to utilisation, encourage research and innovation in utilisation and share best practice. Feedback from the project will be via the individual Lead for each centre. A national meeting, inviting every CLU representative, will then be held on organ utilisation to focus on the outcome and what the next steps should be. It is recognised that this will be probably around April/May.

The first COVID-19 surge showed transplant activity as a 'V' shape, recovering quickly in July/August time. We hope to maintain services better in the second surge and we are in a better position at present.

Professor Pollok thanked J Forsythe for the work undertaken by the NHS in supporting the transplant community.

**4 COVID-19 Liver Transplant**  
**4.1 Liver Utilisation Report – LAG(20)30**  
 Refer to paper.

**5 UPDATE ON THE NATIONAL OFFERING SCHEME**

**5.1 Compliance with sequential data (SDC) submission - LAG(20)31**  
**5.1.1** NHSBT have received 6663 SDC forms between 14 December 2017 and 8 November 2020 across all seven UK liver transplant centres. Of the 382 patients on the elective CLD/HCC transplant list on 8 November 2020, 111 (29%) had not had a SDC form returned to NHSBT within the last 2 months and NHSBT had not received any SDC forms for 67 patients who were on the transplant list for more than one month.

All centres were reminded to send in their SDC forms at least once every three months while the patient remains active on the list to ensure accurate matching runs for the patient's transplant benefit score and to enable the most appropriate ranking on the NLOS.

**5.2 National Liver Offering Scheme (30 months data) - LAG(20)32**  
**5.2.1 Summary points of the 30 Month Report: 20 March 2018 - 19 September 2020.**

- Due to the impact of COVID-19, on 27 March it was agreed that liver centres should consider an elective named patient offer for any patient when offered and not just the named patient. It was also agreed that a kidney would not be held back if a liver/kidney patient was in the top three named elective patients. There were no changes to the DCD offering scheme and the

changes to the DBD offering scheme ceased on 9 July 2020 when named patient offering recommenced.

- A slightly higher proportion of super-urgent patients were registered for their second liver transplant in the thirty months prior than during the thirty months post (26% and 25% respectively). Of the super-urgent patients registered for a second graft, 73% of those registered in the thirty months post had received a DBD transplant as their first transplant compared with 58% in the thirty months prior.
- A higher proportion of new CLD and HCC downstaging registrations were transplanted in the first three months post NLOS than registrations during the same period in 2015/2017. There was a difference between the three-month registration outcome and time period of registration for CLD patients but not for HCC, VS and HCC downstaging patients.
- There were more patients transplanted in the first three months for all age groups apart from the 25-39 age group. There was a higher proportion of first graft patients transplanted but not for re-grafts.
- Table 7 showed that between 20th March 2018 and 19th September 2020, a higher proportion of new registrations were transplanted compared with those active/suspended on March 2018. This was a similar picture in the 24 months report. Data for this table remains a concern. 167 patients have been removed (70 patients more than at 6 months). It would be beneficial to see the details of the 167 patients that have been removed and their survival from point of registration. In addition, it would be useful to extend this to all patients removed since March 2018.
- It was commented in May 2020 that the majority of patients who were active or suspended on 19 March 2018 and remained active or suspended at 2 years had been suspended (N=44), with only 6 remaining active. There is a significant time span for some patients who have waited since registration which has been difficult to explain.
- In the first 30 months of the scheme, 2,398 DBD livers were offered for Transplantation compared with 2,224 during the 30 months prior. Of the 2,398 livers offered, 2,075 (87%) were retrieved and 1,802 (87%) were transplanted (all but 13 were transplanted in the UK). The proportion of DBD livers offered and retrieved is very similar to the percentage for the thirty months prior to the introduction of the new scheme.
- Table 10: Concern has been raised regarding the 273 DBD livers retrieved and not transplanted. This has been raised at the NLOS monitoring group.
- There has been a slight change to the liver and CT offering list. It was agreed that if the lungs were not accepted for a SU lung patient, it would be offered to the liver/CT patients before being offered to lung only patients.
- S Masson is undertaking a separate piece of work looking at the outcome and type of patients transplanted during COVID-19 compared with the same period two years prior.

### 5.3 Feedback from the Monitoring Committee - LAG(20)33

#### 5.3.1 Reasons for non-transplantation

- 5.3.1.1 This will be covered by the work to be undertaken by J Whitney and J Isaac looking at the maximum opportunity for liver organs to be utilised.

**J Whitney/  
J Isaac**

#### 5.4 Options Appraisals for updating the TBS parameter estimates - LAG(20)34

##### 5.4.1 Regular meetings have been held to update the TBS parameters in simulations and to examine the results.

At the last meeting held on 3 November 2020, out of the six simulations presented, simulation 5 was chosen to be the optimal one. This showed the lowest number of deaths and the largest number of patients' life years.

It is not possible to have data for specific disease categories as the information dating back to 2006 is not as clearly defined as now. For example, non-alcoholic fatty liver disease (NAFLD) was included as a metabolic disease group but has now been put into its own category.

Updating the parameter estimates while making an adjustment in the baseline survivor function would appear to provide a suitable adjustment to the TBS but further refinement is required.

Agreement was made to carry on with the work undertaken with further analysis which will be reviewed by the TBS group and LAG Core group.

If a refinement to NLOS is agreed with the TBS parameters updating group and approved by core group it was agreed that this would be advised to LAG members in advance of the next LAG meeting with a view to approving and implementing as soon as possible.

#### 5.5 Further refinements to the National Liver Offering Scheme

##### 5.5.1 Prioritised paediatric patients and offering of split livers - LAG(20)35

###### 5.5.1.1 Prioritised paediatric liver patients

Changes to the Selection and Allocation policies will be made as follows:

The following will be added as section 4.5 (Appeals process section) of the liver selection policy:

4.5 Requests to formally prioritise paediatric patients who are clinically deteriorating will be managed and overseen by the requesting transplant centre who will provide the agreed representatives from the other UK paediatric transplant centres and the chair of the National Appeals Panel with the information required. If formal prioritisation is agreed by the other paediatric centres, the registration should be updated with

4.5.1 Hepatoblastoma as the primary indication

4.5.2 Original primary indication as the secondary indication

4.5.3 Other please specify as the tertiary indication with "PRIORITISED PAEDIATRIC PATIENT" added in the freetext for other indication.

###### Liver splitting – offering of right lobe

###### Point of offering right lobe:

It was agreed that the left lobe should initially be offered to paediatric centres and centres with small adult patients. When the offering outcome of the left lobe is known then the right lobe or the whole liver will be offered to named adult and large paediatric patients according to the offering sequence. This has been implemented and the impact of this change on the length of the offering process is currently being investigated.

Changes to the Selection and Allocation policies will be made as follows:

- 5 Section 2.9.1.9 of the Liver Allocation policy will be updated to:  
If a liver is initially offered as a whole graft and the accepting centre **anticipate the liver will be split regardless of whether the donor meets split criteria**, then the initially accepting centre should inform ODT Hub Operations when accepting the liver which segments not required (e.g. right lobe) needs to be offered nationally through either the national liver transplant offering scheme or through the Fast Track scheme if a fast track trigger points has been reached. This applies to all offering tiers.

#### Liver splitting – Hepatoblastoma

Changes to the Selection and Allocation policies will be made as follows:

- 6 Section 2.9.1 of the Liver Allocation policy will be updated to:  
2.9.1 All such donors must be offered for splitting unless there are super-urgent, multi-visceral, combined heart/liver or combined lung/liver patients waiting (see Figure 1).

### 5.5.2 **ACLF patient prioritisation – LAG(20)36**

5.5.2.1 A new tier in the offering scheme was recommended after paediatric offering but requires an IT change. Until the IT change is implemented the interim patient priority process will be SU, hepatoblastoma, multi-organ (liver/intestinal and liver/cardiothoracic), paediatrics and then adults.

It was agreed ACLF patients can be offered in the hepatoblastoma tier; similar to the formally prioritised paediatric patients, offered after genuine hepatoblastoma and prioritised paediatric patients and be prioritised by waiting time.

It was anticipated that there would not be many ACLF registrations; a process and standard operating procedure and data collection tool is being developed for implementation in early 2021.

### 5.5.3 **Offering to multi-organ patients – LAG(20)37**

#### 5.5.3.1 Liver and cardiothoracic patients

It was agreed with the Chairs of CTAG and LAG that named patients would be offered after cardiothoracic organs offered to super-urgent patients but prior to elective offering. The new liver/cardiothoracic tier on cardiothoracic matching runs (agreed at CTAG) will require an IT change and has been implemented manually in the interim.

#### Liver and intestinal patients

Changes in the bowel donation criteria have been agreed at MCTAG.

Hepatoblastoma liver/intestinal patients offered through liver/intestinal tier will be prioritised above other liver/intestinal patients but after the hepatoblastoma liver tier. The offering pathway for liver/intestinal patients who would also like liver only offers will be to be determined on a case by case basis.

Both were approved by LAG.

### 5.6 **Maximum number of livers offered to any one centre – LAG(20)38a & b**

At the weekly COVID-19 liver meetings, it was agreed that the maximum number of liver offers accepted (for both DBD and DCD) per adult programme will be three at normal times and two during periods of the COVID crisis. The following points are also to be adhered to:

- The three adult and paediatric liver transplant centres can consider paediatric offers in addition to their adult allocation but must be able to facilitate the totality of the accepted offers.
- An accepted offer is considered closed when the transplant is completed or at the point where the organ is declined for another reason.
- Centres which have reached the maximum number of accepted offers, will continue to receive further offers, but if they are to accept an offer beyond the maximum number, they will have to decline a previously accepted offer but only until the point of the arrival of the NORS team at the donor hospital.

If a centre requests a back-up for one accepted offer, they should not accept another.

The proposal was approved by LAG.

## 6 UPDATE FROM FTWUs

### 6.1 Neuroendocrine Tumours – LAG(20)60

6.1.1 The FTWU was asked to examine NET tumours as an indication for transplantation. The next stage is to perform 50 liver transplants starting early 2021 but this will depend on LAG to decide how to allocate organs for this programme and how patients are to be assessed. Patients will be immuno-suppressed for the first three months. The protocol will also outline how patients are to be followed up and an MDT and a co-ordinator will be required. The collection of data will be key to the study to monitor the outcome of patients as they are transplanted and to decide on what the real criteria is for outcome. It was stated that NHSBT do not have the capability to gather data centrally. Agreement needs to be reached on what data is to be collected by the centres. It is hoped that there will be some patients registered by the next LAG meeting in May.

It was stated that this is a complex area in which to build a transplant programme and we do not have expertise on a national level in the UK. It was recommended that rather than the NHSBT and LAG run the study, it would be more appropriate for a national MDT to give guidance to centres. It was agreed to have a zoom meeting to move this forward.

### 6.2 Minimal Listing criteria for HCC

6.2.1 Membership of the FTWU group has now been finalised and the first meeting is scheduled for 2<sup>nd</sup> December 2020.

### 6.3 Cholangiocarcinoma – LAG(20)39a & b

#### 6.3.1 Hilar Cholangiocarcinoma

Liver transplantation has to be performed within 3 months of listing and it has been agreed that some form of enhanced priority for organ allocation should be provided. This would be similar to the allocation for hepatoblastoma children where a window for transplantation is defined. Patients will receive proton radiotherapy in one of the NHS facilities. This would require approval by NHS England. The plan is to assess five patients initially and to stop the programme in the event of any deaths.

#### Intrahepatic CC

Patient selection would be for tumour size less than 2 cm (though there is a question of whether to undertake biopsy or not) and there would be some form of enhanced status for organ allocation similar to allocation for hepatoblastoma children where the window for transplantation is within two

weeks of listing. The next step is to form a delivery group to flesh out the protocol in more detail and work with centres to create a delivery programme.

#### **6.4 Hepatopulmonary syndrome patients – LAG(20)40**

6.4.1 An FTWU, led by Jo Leithead, was set up to look at why patients with HPS were not getting transplanted in a timely manner. Currently patients being listed are based on a UKELD less than 49. Based on post data from the 15 months NLOS report, this would take two years for patients to be transplanted under variant syndrome.

The FTWU defined the new selection criteria for HPS patients to be listed as chronic liver disease (CLD) with UKELD  $\geq 49$  or variant syndrome. All patients, mild and severe, will be recorded on the waiting list and reviewed after every three months. Patients should ideally be transplanted before they develop severe disease when outcomes could be adversely affected. The next step is to work out identifying these patients and prioritising them which the current scheme does not.

#### **6.5 HCV positive transplants into HCV negative recipients – LAG(20)41**

6.5.1 There has been a lack of uptake for this type of transplant from different centres. An education programme will be run to help overcome centre attitude and barriers. A Elsharkawy will design some questions for the first survey to move the programme forward.

### **7 LIVER TRANSPLANT COMMISSIONING**

#### **7.1 NHS England**

Aspirant Market Entrants (AMEs) is a process for the submission of proposals to increase the number of centres commissioned via highly specialised service (HSS) provision or to add to the number of HSS providers in a specific market. Two proposals have been submitted, one from Plymouth and one from Liverpool. RDAG (Rare Diseases Advisory Group) who make recommendations to NHS England are looking for a 360 degree feedback from individuals, transplant centres and Advisory Groups. It was highlighted that RDAG are looking for a view for the next step for liver transplant rather than to accept the proposals. D Thorburn is co-ordinating a response on behalf of LAG. There will be an open forum to help prepare a response and the letter will be will shared with LAG members prior to submission.

Initial comments received at LAG were:

- governance, the transfer of skill set and back up as well as the financial cost of this is not covered. A SWOT analysis should be undertaken.
- Is there an unmet need for liver transplantation? Should increased transplantation be met through existing pathways or other pathways? This is an opportunity to look at improving the service throughout the UK.
- Is this the right time to be creating a new liver transplant centre?
- British Liver Trust stated that liver care is more than patchy and a campaign has been set up called the "Sound the Alarm" regarding early diagnosis and has received 14,000 registrants to-date.

#### Post meeting note:

A meeting was held on 26 November to seek the response from LAG members to respond back to NHS England by the 7<sup>th</sup> December.

## 8 GOVERNANCE ISSUES

### 8.1 Non-compliance with allocation

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

### 8.2 Governance

#### 8.2.1 Governance Report – LAG(20)42

8.2.1.1 Owing to the decrease in activity in the period since the last LAG meeting there has been a decrease in incident reports and therefore there are no relevant cases to report on.

D Manas requested the need for good communication when taking the OrganOx to centres, which should include senior staff and not be confined to junior staff.

NHSBT requested if photographs of the damage, at retrieval and preferably at the centre, could be included when submitting an incident to ODT Clinical Governance. This would aid learning for the NORS team and for the investigation of each case.

### 8.3 CUSUM

#### 8.3.1 Summary of CUSUM monitoring of outcomes following liver Transplantation – LAG(20)43

Over the last six months, there has been one signal against the national rate for adult elective liver transplantation.

#### 8.3.2 Report on recent triggers (shared learning)

8.3.2.1 All preceding triggers have now been closed.

##### Post meeting note:

The CUSUM Signal Trigger 213: Lessons Learned for Cambridge was circulated to LAG members on the 24<sup>th</sup> November.

D Manas reported that work is being undertaken on a CUSUM type score for injury on damage to organs from retrieval to implanting. This will be part of an electronic replacement for HTA.

#### 8.3.3 Updating the expected mortality rates – LAG(20)45

8.3.3.1 The current expected rates are based on first, NHS group 1, deceased donor liver only transplants in the UK between 1 January 2012 and 31 December 2015. National mortality rates have decreased since 2008, in particular for both paediatric elective and super-urgent transplants where there have been 10 and 4 deaths within 90 days respectively since 1 January 2012.

The expected baseline will be moved to transplants performed between 1 January 2015 and 31 December 2018 for both adult and paediatric transplants.

## 9 STATISTICS AND CLINICAL STUDIES (SCS) REPORT

### 9.1 Summary from Statistics and Clinical Studies – LAG(20)46

9.1.1 A summary of the current and future work undertaken by Statistics and Clinical Studies was given and the latest list of staff responsibilities. There are three clinical fellows working with the Statistics team across organ

transplantation; in abdominal organ utilisation, malignancy transplantation and cardiothoracic transplantation.

There is a clinical trial taking place using machine perfusion Called the PLUS trial which will commence in early 2021

## **10 FOLLOW-UP FORM RETURN RATES IN ANNUAL REPORT ON LIVER TRANSPLANTATION – LAG(20)47**

- 10.1** Concern was raised regarding the impact of low form return rates in July. Centres are asked to ensure follow-up is up to-date to enable NHSBT to accurately monitor liver transplantation.

## **11 CLINICAL LIVER TRIALS AND TRANSPLANTATION**

### **11.1 Donor Simvastatin Treatment – LAG(20)48a & b**

The details of a donor management trial, comprising the randomisation of multi-organ donors to receiving treatment with simvastatin or placebo, were presented by Professor John Dark.

In a previous study, the use of simvastatin (which has anti-inflammatory properties) in heart donors showed improved cardiac survival and reduced early complications and reduced rejection. In the same study, kidneys showed no difference, livers demonstrated a lower ALT at day 7, lungs showed improved primary graft dysfunction grade: no multi-visceral transplants were undertaken.

This 4-year study (largest randomized study) will use 2600 randomised DBD adults, following consent for donation to receive a single dose of 80 mg simvastatin. The recipients will not be known; this is a donor intervention management study and will require MHRA approval. The concept of the study has been presented to a number of PPI groups who have all approved and is being presented at all relevant Transplant Advisory Groups. MCTAG have approved the study.

There is an advantage of undertaking the study in the UK owing to the national transplant services being coordinated centrally.

Any comments can be sent direct to John Dark and Chris Watson.

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

### **12.1 Report from the Multi-Visceral & Composite Tissue Advisory Group Meeting - 21 October 2020**

- 12.1.1** Refer to AP 10 in Section 2.2 – Action Points.

## **13 ANY OTHER BUSINESS**

### **13.1 Special Interest Group – Transplant Oncology**

- 13.1.1** The Special Interest Group was formed from BLTG, led by R Prasad, and is a diverse group of health care organisations representing e.g. hepatologists, radiologists, pathologists, oncologists etc and patient and public representatives to contribute to developing protocols, guidelines and datasets working closely with LAG and NHSBT.

13.1.2 A request was made from J Asher for a couple of volunteers to test a SABTO guidance for infection and disease on whether an organ would be safe to accept based on the disease in the donor and the level of urgency of the transplant. Individuals interested can contact J Asher for further details (j.asher@nhsbt.nhs.uk). After the 18th December the email address is [john.asher@ggc.scot.nhs.uk](mailto:john.asher@ggc.scot.nhs.uk)

**13.2** New Chairs

RINTAG: Gavin Pettigrew starting 1<sup>st</sup> November 2020

PAG: Steve White starting 1<sup>st</sup> December 2020

**14** **Date of next meetings:**

- Wednesday 19 May 2021 - MS Teams Video Conferencing.
- Wednesday 24 November 2021

**15** **FOR INFORMATION ONLY**

The following papers were attached for information to members:

15.1 Transplant activity report: October 2020 - **LAG(20)49**

15.2 Group 2 Transplants - **LAG(20)50**

15.3 Outcome of appeals - **LAG(20)51**

15.4 Activity and organ utilisation monitoring (dashboard) - LAG(20)52

15.5 Removed

15.6 HCC Downstaging - **LAG(20)55**

15.7 Transplant Recovery document and related COVID-19 documents

<https://nhsbtdeb.blob.core.windows.net/umbraco-assets-corp/19002/pol296.pdf>

Second Surge Planning  
(October 2020)



Pol301.2 Second  
Surge Planning 20.10

LPTC Letter



LPTC response to  
COVID 19 second wave

Liver Transplant  
Passport



Liver Transplant  
Transfer Minimal Data

Testing



J Forsythe  
07.10.2020 Testing.pc

Assessment & Screening



POL304-1 SARS  
CoV-2 Assessment &

15.8 Minutes of the Multi-Visceral & Composite Tissue Advisory Group meeting:  
11 March 2020 - **LAG(20)56**

15.9 Minutes from the Retrieval Advisory Group: 31 March 2020 - **LAG(20)57**

15.10 QUOD statistical reports - October 2020 - **LAG(20)58**

15.11 IT September Report - **LAG(20)59**