

**NHS BLOOD AND TRANSPLANT
ORGAN AND TISSUE DONATION & TRANSPLANTATION DIRECTORATE
MINUTES OF THE FORTY-SECOND MEETING OF THE
LIVER ADVISORY GROUP
HELD ON WEDNESDAY 27 APRIL 2022**

ATTENDEES

Douglas Thorburn	DT	Chair, Liver Advisory Group / Royal Free Hospital
Anya Adair	AA	Royal Infirmary of Edinburgh
Mark Aldersley	MAI	Leeds Teaching Hospital
Michael Allison	MA	Hepatology, Addenbrooke's Hospital
Varuna Aluvihare	VA	Kings College Hospital, London
Magdy Attia	MAt	Leeds Teaching Hospital
Richard Baker	RB	Assistant Medical Director for Governance, NHSBT
Jenni Banks	JB	Statistics & Clinical Research, NHSBT
Joan Bedlington	JBe	Patient Representative
Andrew Butler	AB	Chair MCTAG / Addenbrookes Hospital
Lee Claridge	LC	St James Hospital, Leeds
Becky Clarke	BC	Specialist Nurse OD Representative, NHSBT
Ahmed Elsharkawy	AE	University Hospitals, Birmingham
Paul Gibbs	PG	Addenbrookes Hospital, Cambridge
Pamela Healy	PH	Chief Executive, British Liver Trust
Andrew Holt	AH	University Hospitals, Birmingham
John Isaac	JI	Deputy Chair LAG / University Hospitals, Birmingham
Satheesh Iype	SI	Royal Free Hospital, London
Maria Jacobs	MJ	Statistics & Clinical Research, NHSBT
Kavitha Jayaprakash	KJ	St James Hospital, Leeds
Derek Manas	DMM	Medical Director, OTDT, NHSBT
Aileen Marshall	AM	Royal Free Hospital, London
Steven Masson	SM	The Freeman Hospital, Newcastle upon Tyne
Sarah Matthew	SMa	Lay Member
Joerg-Matthias Pollok	JMP	Royal Free Hospital, London
Krishna Menon	KM	Kings College Hospital, London
Raj Prasad	RP	Liver CLU / St James Hospital, Leeds
Katie Quist	KQ	Recipient Co-ordinator Representative
Ian Rowe	IR	Chair of the National Liver Offering Scheme Monitoring Committee
Peter Robinson-Smith	PRS	Recipient Co-ordinator Representative
Khalid Sharif	KS	Birmingham Women's Hospital
Kenneth Simpson	KSi	Royal Infirmary of Edinburgh
Laura Stamp	LS	Lead Nurse Recipient Coordination, NHSBT
Rhiannon Taylor	RT	Statistics and Clinical Research, NHSBT
Steve White	SW	Chair PAG/ The Freeman Hospital, Newcastle upon Tyne
Julie Whitney	JW	Head of Referral and Offering, NHSBT

IN ATTENDANCE: Alicia Jakeman, Medical Director & Group Support, NHSBT

APOLOGIES: Ayesha Ali, Chris Callaghan, Ian Currie, Anushka Govias-Smith, Tassos Grammatikopoulos, Thamara Perera, Sanjay Rajwal, Mick Stokes, Sarah Watson

ITEM		ACTION
1.	<p>Declarations of interest in relation to the agenda <i>It is the policy of NHSBT to publish all papers for this meeting on its website unless the papers include patient identifiable information, preliminary or unconfirmed data, confidential and commercial information or will preclude publication in a peer-reviewed professional journal. Authors of such papers are asked to indicate whether their paper falls into these categories.</i></p>	
2.	<p>Minutes of LAG Meeting of 24 November 2021 – LAG(M)(21)2</p>	
2.1	<p>Accuracy The Minutes of the meeting of 24 November 2021 were accepted as a true and accurate record.</p>	
2.2	<p>Action Points - LAG(AP)(21)02 All action points were either completed or included on the agenda.</p>	
2.3	<p>Matters Arising, not separately identified There were no issues raised at the meeting.</p>	
3.	<p>Medical Director's Report DT raised the current paediatric hepatitis cases, with 117 cases reported so far with ten transplants. He highlighted the technical briefing from UK HSE published on the 25th of April, which gives up-to-date information. DMM confirmed that he communicates regularly with the HSA. DT chairs two weekly centre directors' meetings for adult and paediatric centres, there is no spill over into the adult population. VA asked if the group could look again at the SOP for a super urgent appeal so that they don't completely distinguish between indications and contraindications as being a qualifying rule for an appeal, following a recent complex case. A discussion ensued that the appeals process was designed for patients who didn't fulfil minimal listing criteria rather than to determine futility or to seek a level of prioritisation. DT will pick this up with core group outside of this meeting.</p>	DT
3.1	<p>Organ Donation and Transplantation Update DMM updated the group on new appointments, congratulating them on their new roles - six new AMDs have been appointed, reported directly to DMM; Lorna Marson is the new Associate Medical Director for R&D, Richard Baker is now the Assistant Medical Director for Governance, Sanjay Sinha is the surgical Lead for Governance, supporting R Baker. Lisa Burnapp will be leading on liver, as she is leading on the living donor liver program and will be attending future LAG meetings</p>	
3.2	<p>Organ Utilisation Group (OUG) and Programme (OUP) DMM informed the group that OUG, chaired by Steve Powis, looking at certain issues such as new technologies, education and digital infrastructure. Their recommendations should be released June 2022, it is expected that potential recommendations will include workforce, recipient outcomes, organ utilisation using new technologies and digital infrastructure. DMM reported that funding has been secured for the CLU programme for Q1 and in terms of ARCS, the FTWU for liver perfusion has been reported.</p>	
3.3	<p>Liver Utilisation Report for noting - LAG(22)02</p>	

	This report was circulated prior to the meeting.	
4.	Update on the National Liver Offering Scheme	
4.1	<p>Compliance with Sequential Data Submission - LAG(22)03</p> <p>RT presented the paper, reporting on the elective liver SDC form return rates as at 6 April 2022. Over 10,000 sequential forms from all seven transplant centres, for just under 3000 patients, have been received. The median number of forms is 2 per patient. Three of the seven transplant centres have submitted a median of three SDC forms per patient. There are 71 patients who've been active for at least 31 days and where sequential forms haven't been received.</p>	
4.2	<p>Follow-up for return rates in Annual Report on liver transplantation - LAG(22)04</p> <p>RT presented the follow-up form return rates paper, looking at the form return rates at 3 month, 6 month and lifetime follow-up, that will be reported in the annual report. Lifetime follow-up returns rate varied between 27% and 98% between adult centres. It has been previously agreed that survival rates for centres with a return rate of less than 80% won't be reported within the annual report. JW reported that to compliment this data, she will start sending out a dashboard on a monthly basis rather than having this report at the end of the year alone.</p>	
4.3	<p>National Liver Offering Scheme (48 month data) and Summary Feedback of Key Points from NLOS - LAG(22)05</p> <p>IR discussed the report, following changes to how the data is presented. He advised that it is difficult to identify what changes to outcomes identified are due to implementation of the NLOS and what changes result from the COVID-19 pandemic. However, elective registrations have been impacted by COVID-19, particularly during the peak activity periods but not during the Omicron surge.</p> <p>IR reported that, in terms of outcomes on the waiting list there's been a noticeable decrease in the number of patients who are being transplanted at early time points. For instance, at three months after registration in the year 2019/2020, it was 50% of patients who've been registered, in 2021/2022, it's down to 40%. This appears to be as a result of decreased DBD donor numbers which have not recovered to pre pandemic levels. Despite that reduction in early transplantation, waiting list mortality has returned to 6% at 6 months, lower than it was in the year before the introduction of NLOS. This suggests that there is a sustained positive benefit following the introduction of the national liver offering scheme.</p> <p>Following the concern expressed in the LAG meetings regarding re-transplantation, it's clear from the report that there is a higher proportion of patients in the re-graft group that are being removed or who are dying on the waiting list when compared to first transplant patients. The acceptance rate is lowest for re-graft candidates yet they're the third most commonly offered to group. When you compare with the other two commonly offer groups, alcohol and metabolic, the proportion of offers accepted for those</p>	

	<p>two groups is about 40%, it's less than 20% for regrant. IR highlighted that the median number of offers to a retransplant patient where the liver was ultimately transplanted is zero. 71% of patients who died on the waiting list received no named patient offers.</p> <p>AM asked if there was evidence of an impact on age and waiting times. IR advised that there were no removals in the 17-25 group over the whole period of NLOS but that the rate of transplantation in those younger age groups is lower, meaning that they are spending more time on the waiting list.</p> <p>DT advised that there have been discussions on extending follow-up to ten years as a measure of utility and factors that affect post-transplant outcomes which may have an increasing impact on M2 survival versus M1 survival. IR stated that M1 has such a dominant effect on the score, that change to M2 would not change the priority currently and that increasing age of the patient will always be a strong influence on lowering M1 compared with any detrimental effect on M2.</p> <p>IR informed the group that he is going to extend into the monitoring report, all patients who've been removed from the waiting list to see whether there are ways that the monitoring committee can identify groups that are potentially being disadvantaged, but that is being compensated for by the use of grafts offered through the fast track or DCD donors.</p>	
4.4	<p>Updating the TBS Parameter Estimates</p> <p>RT provided a verbal update with the updates completed for the LAG meeting in November and the agreement that non-significant factors would be removed from the models to make it simpler to understand. These changes have been raised with IT and they are currently undertaking some system testing, with the hope that the update will be released later on this year.</p>	
4.5	<p>Future Work</p> <p>DT discussed the areas of future work highlighted at the last LAG meeting;</p> <ul style="list-style-type: none"> - reviewing minimal listing criteria with a potential move from using UKELD to M1 (estimated survival on the list). This is considered worthwhile but not a priority - inclusion of DCDs in NLOS. It was agreed this should wait until NRP is more widely established. 	
4.6	<p>Impact of NLOS on retransplant patients - LAG(22)06</p> <p>RT shared her paper looking at the impact of the national liver offering scheme on patients on the list during the first 48 months of the offering scheme. Looking at outcomes of patients who were either on the list on the 20th March 2018 or were a new registration during the four years, there have been 4251 registrations of which 67% have been transplanted.</p> <p>For regrant patients, there were 348 registrations active on the list in this time period, of which 60% have been transplanted and 16% died or removed from the list. Looking at the demographics of the 348 regrant registrations, the percentage transplanted ranges</p>	

	<p>between 52% for 40-49 year olds up to 71% for 60 plus. There were six patients registered for their fourth liver transplants and of these 83% received before the transplant and for patients who are registered for a second transplant, 60% have been transplanted.</p> <p>Discussion was held regarding variation in individual centre responses to the number of named patient offers by centre. VA will share his data on King's patients with RT & DT.</p> <p>DT stated that the report highlighted that outcomes for those patients transplanted with DCD and with fast track livers are similar to the those that are transplanted with named patient offers. PG reported that at Addenbrookes they are not offered DBD livers and use NRP DCD and also the Organox machine. MA asked if all centres are listing the same type of patients and using the same threshold and that this may require further analysis to gain an understanding of which patients are being listed for re-transplantation making it as consistent as possible between centres. DT advised that this will be taken back to LAG Core Group for further discussion. Furthermore, a comparison of outcomes on the waiting list prior to NLOS with the post NLOS should help clarify whether NLOS has had an impact on waiting list outcomes for retransplant patients.</p>	<p>VA</p> <p>DT</p>
4.7	<p>Inclusion of DCD livers in NLOS Please see agenda item 4.5</p>	
4.8	<p>Flight costs - LAG(22)07 RT presented her paper, with the audit being part of the operational monitoring of the implementation of NLOS and following concern at the last LAG meeting regarding how much money is being spent and how many flights were arranged between September 2021 and February 2022. There were 73 flights arranged with a total cost of just under £700,000 in total. 19 livers were flown where the journey time was less than five hours, 8 of them had a journey less than four hours, which is the cut off between road and flight.</p> <p>DT raised concern that the flights are for DBDs named patient offers, rather than Fast Tracks and Super Urgent transplants. JW advised that new operational systems are in place. When a flight is requested, the centre now is also given the equivalent cost and time for that equivalent journey by road. Co-ordinators will be able to see the two key differences at the point of booking due to the cost difference to only gain 15/20/30 minutes with a flight versus the road mileage.</p> <p>Centres were encouraged to reflect on the findings and consider how flights were used within their centre.</p>	<p>Centre reps</p>
5.	Update from FTWUs	
5.1	<p>Colorectal liver metastases - LAG(22)08 DT asked if the group had any questions or comments on the paper, previously circulated to the group. KM advised that the FTWG concluded that there should not be a national MDT but a national specialist review board. A national meeting is due to be held on 17th June, to discuss the roll out the three indications.</p>	

	<p>KM concluded that the pathway starts when the patient meets the listing criteria and, they go through the same implementation process for the coming to the transplant centre, being discussed at an HPB meeting, then to a listing meeting. If there is a lack of clarity in whether the patient can be listed, they will then go to the national Specialist Review Board, formed by people who are part of the FTWU.</p> <p>Jl asked if, after the June 17th meeting, if the group can put something in place to detail what the final steps before being open for referrals. DT agreed that a recommendation about the point of referral would be helpful to protect and guide the colorectal and transplant teams. KM identified this as being stable for 18 months within listing criteria being the point where consideration for referral to the LT MDT should occur.</p>	KM
5.2	<p>Minimal Listing Criteria for HCC - LAG(22)09a&b</p> <p>DT presented the papers produced by Abid Suddle, previously submitted to LAG and LAG Core Group. He detailed the recommendations that if there was a tumour that was less than two centimetres in size in somebody with good synthetic function, it would be inappropriate to move them onto the transplant waiting list. They are going to establish an appeal process that would support centres asking to register patients of that nature.</p> <p>Discussions have also about single lesions that were two to five centimetres in size, concluding that those patients should be directed towards resection rather than transplantation.</p> <p>Following the recommendation that non transplant approaches should be taken, a prospective audit would be run by HCC UK to gather information on those patients with single lesions 2 to 5 centimetres, to understand the decision making of the centres and why they've recommended transplantation over other therapies.</p> <p>Jl recommended they form a small group for HCC to sort of sense check the appeals and have a checklist to work through, rather than a large team which could monitor and report outcomes. The group are supportive of having a limited HCC specialist group to review the cases, giving consideration to paediatric cases also.</p> <p>An appeals group would be established to consider cases where registration was being sought for single lesions <2cmHCC UK to propose an audit of registration of single HCC</p>	
5.3	<p>Cholangiocarcinoma - LAG(22)10</p> <p>RP gave a verbal update on the delay to the to the implementation process due to delays with the PBT commissioning. This will now go through a commissioning evaluation with the implementation process in anticipated in September/October 2022.</p> <p>DT informed the group that it was important to adopt the Four Nations approach as PBT is only currently available in Manchester and London and at the point of opening all patients in other parts of the United Kingdom should have access to it as well. During Liver centres calls the group have tried to encourage</p>	

	Commissioners to discuss this particular issue and are hopeful that once it goes through with NHS England that the other Commissioners will adopt this without long delays.	
5.4	<p>Machine Perfusion Working Group - LAG(22)11a-c DT informed the group that the FTWG, chaired by Chris Watson, have worked really hard to come back with recommendations advising that the background is that they're trying to support standardisation of the use of perfusion technology in liver transplantation around technology selection, donor organ selection, etc.</p> <p>Jl advised that the group have created protocols, detailed criteria in terms of usability of livers, guidelines on parameters and a detailed protocol on the accompanied liver. Jl suggested amending CW's paper into a guidance document that can be disseminated to all centres. Lastly, Jl advised the group will need to look at data collection and reporting on adverse outcomes and for a forum for learning and discussion.</p> <p>DT advised that the HTA are guided by what NHSBT recommends, if NHSBT recommend that the organs need to always be accompanied, that's what HTA will support, equally if they said it was acceptable for them not to be accompanied, the HTA would accept that. An SOP will be required to describe the process clearly as to how to manage the organ or manage the equipment, alarms etc. If there was a loss of integrity of the system or the organ during the transportation, would the organ be discarded? DT agreed that LAG accepts all the recommendations,</p> <p>LAG also agreed that standing group should be established oversee clinical governance of national machine perfusion, review the data, ad verse events and performance and outcomes against the guidance. DT to approach Chris Watson in this regard.</p> <p>An SOP to be produced to describe how organs should be dealt with when the system alarms in transit when unaccompanied.</p>	<p>DT</p> <p>Chris Watson</p>
5.5	<p>ACLF - LAG(22)12 DT presented the paper which details one ACLF case per month. The median length of stay per patients is fifteen days on ICU, with a thirty day plus overall length of stay. He advised that registering patients on the ACLF tier outside working hours is currently not feasible as it requires a manual workaround to get the patients activated to the list.</p>	
5.6	<p>Neuroendocrine Tumours - LAG(22)13 DT presented T Shah's paper, from go-live there have been seven patients discussed in the national MDT, but no registrations. DT queried how much demand there is for registering patients for this indication.</p>	
5.7	<p>HCV Positive Transplants into HCV Negative Recipients - LAG(22)14 JW presented AE's report, all centres now have permission to utilise this program and are receiving offers. There have been five liver transplants from positive donors, transplanted at four liver transplant centres, offered via the positive virology route. The</p>	

	<p>recipient co-ordinators are meeting to go through centres lists to collate numbers for each centre.</p> <p>LAG agreed that when we got to 75% of every centre's lists they would consider going to named patient offers, or sequential offering rather than fast tracked by centre.</p> <p>DT agreed that this work was important as there are still 15% of organs that are being declined because of the virology and there's no suitable recipient, which would suggest that not all potential candidates are being consented. He advised that these are a group of DBD organs that could be used with good outcomes. This will encourage centres to have conversations with their patients and encourage them to consider these organs.</p>	
5.8	<p>UKTR Data Collection</p> <p>IR provided a verbal report that work is still ongoing, trying to review what data collection for 2022 should look like. DT confirmed that the rate limiting step is likely to be the IT changes that sit behind any alteration and the data collection that is being recommended.</p>	
6.	Liver Offering for New Indications	
	RT commented that it will be updated in the liver selection policy to detail the service evaluations of the new variant cancer indications added to the variant list. These patients will then be open to the variant syndrome pathway.	
7.	Liver CLU Scheme and Liver Utilisation	
	RP provided a verbal report on the CLU scheme, acknowledging support from DT, JI and the OUP. He provided an update on the national offer review scheme, looking at what high quality livers have been declined and provide a report for November's LAG meeting. Also at a national level, the group are looking at the issues around right lobe grafts and their utilisation and the surge in DCD utilisation to again provide a formal update in November's LAG meeting.	RP
8.	RAG Update – National NRP development	
	IC gave his apologies for the meeting.	
8.1	<p>Super-urgent liver pathway update</p> <p>JW provided a verbal update, recapping that this was implemented last April, with an opt in for Centres as it wasn't being used as hoped. In November NHSBT went to an automatic super urgent liver pathway. 33 super urgent patients have been listed and there have been 26 super urgent liver transplants. In that period of time there have been 187 non-SU liver transplants. JW reported that it has taken about an hour off of the pathway for super urgent liver recipients. A group complete a twice monthly review of all livers accepted on the super urgent pathway, looking at key themes and key issues along the pathway to see how they can continue to make improvements. Their message is that the communication between the Abdominal teams and cardiothoracic accepting teams is critical in reducing time delays.</p>	
8.2	<p>Paediatric offering pathway update</p> <p>JW reported that there were concerns raised around the timings and pressures on paediatric centres with the ideal being night-</p>	

	time retrieval, daytime transplants A group are meeting to optimise the pathway, with their second meeting in four weeks' time.	
9.	Liver Transplant Commissioning	
9.1	NHS England SW and AA have given their apologies. SW asked for any queries to be emailed to her outside of the meeting.	
10.	Governance Issues	
10.1	Non-compliance with allocation	
10.2	HTA B forms - LAG(22)15 RB confirmed that there has been great improvement in the return of HTA B forms, with only one outstanding form on this report. JW advised that the new chase process for the forms appears to be working, having to send out very few reminders at the 33-day point. Further changes will be made if centres can nominate a person for the 33-day chase email to be sent to.	
10.3	Governance	
10.3.1	Governance report - LAG(22)16 RB confirmed that incidents are returning to normal levels of activity, there are no issues at present. DMM highlighted the rules on photography, that images and videos can only be stored on NHSBT & Trust devices, with SNODS using NHSBT Ipads if required. A SOP has been published on the website.	
10.4	CUSUM DMM reported that there is only one centre signal which is currently being investigated with some outstanding information required before this can be closed.	
10.4.1	Summary of CUSUM monitoring of outcomes following liver transplantation - LAG(22)17 No new triggers	
10.4.2	Report on recent triggers (shared learning) Nil to share	
11.	Statistics and Clinical Research Report	
11.1	Summary from Statistics and Clinical Research - LAG(22)18 RT discussed the paper looking at recent applications, highlighting that NHSBT has published risk communication tools for all organs on the website, the tools are designed to support conversations between patients and clinicians at the time of listing, regarding the risks and benefits of transplantation. RT confirmed that IT testing is underway to update the parameters.	
12.	Multi-visceral and Composite Tissue Advisory Group (MCTAG)	
	AB reported on two items, one of which was that we are looking to try to centralize characterisation of chimerism from a bowel transplantation point of view. This is significant because the rates of GvHD are more substantial than for other solid organs, and at the moment all of the centres are struggling. It's taking up to three	

	<p>weeks to get results back, trying to centralise this so the all the samples get sent to one unit might achieve a better turnaround time, He asked if the liver transplant groups other centres may be interested in joining in with to try to justify the cost associated with them. With a central unit the result could be turned around within a week or possibly even within 48 hours. VA agreed to speak with his Haematologist to identify what the obstacles may be to delivering that.</p> <p>Secondly, following previous discussions on utilisation of a split liver for multivisceral transplantation AB feedback regarding a recent full adult multi-vesceral transplant involving a right lobe.</p>	VA
13.	<p>AOB VA raised his concerns that centres were being asked for third opinions and a possible pathway where a patient could go to all centres to be considered for a transplant. AA agreed that is something that should be discussed on a case by case basis, this should not be setting a precedent moving forward. PH agreed that the British Liver Trust are very uncomfortable about this particular case. No stipulation of a single second opinion has been made albeit that a single second opinion should be encouraged. When the patient requests a further opinion and the original centre is supportive, an approach to the LAG chair is justified to consider seeking a further view from another centre.</p>	
14.	<p>Date of next meeting Wednesday 2nd November 2022, venue TBC</p>	
15.10	<p>IT Changes and Update – LAG(22)27 (Liver splitting criteria, FT trigger, Update of NLOS & Crossmatch) DT asked for IT Colleagues to be invited to the November LAG meeting, to provide an update.</p>	AJ
15.11	<p>SIGNET Study update - LAG(22)28 DT advised the group of the SIGNET Study, the study of simvastatin use in donors being led by John Dark and Dan Harvey. They have provided an update that if researchers are considering developing research studies in the context of liver transplantation, they should have a discussion with this SIGNET team about co-enrolment, so that it should be feasible to recruit patients into both studies.</p>	

April 2022