NHS BLOOD AND TRANSPLANT
ORGAN DONATION AND TRANSPLANTATION DIRECTORATE

THE FOURTEENTH MEETING OF THE NHSBT CTAG(L) LUNGS ADVISORY GROUP ON THURSDAY 26TH SEPTEMBER 2019 11:00-16:00 AT CiARB, 12 BLOOMSBURY SQUARE, LONDON, WC1A 2LP

PRESENT:

Jayan Parameshwar (JyP)	**CTAG Chair**, Royal Papworth Hospital
Martin Carby (MC)	**CTAGL Deputy Chair**, Lung Surgeon, Harefield Hospital
Mo Al-Aloul (MAA)	Respiratory Physician, Wythenshawe Hospital
Ayesha Ali (AA)	Highly Specialised Services, NHS England
Lyn Ayton (LA)	Transplant Managers Forum Representative
Marius Berman (MB)	Joint Associate Clinical Lead Organ Retrieval, NHSBT
Paul Brookes (PB)	BSHI Representative, NHSBT
Pedro Catarino (PC)	Centre Director, Royal Papworth Hospital
Diana Garcia Saez (DGS)	Lung Physician, Harefield Hospital
Margaret Harrison (MH)	CTAG Lay Member, NHSBT
Derek Manas (DM)	Joint Clinical Governance Lead, NHSBT
Jorge Mascaro (JM)	Centre Director, Queen Elizabeth Hospital
Lisa Mumford (LM)	Head of ODT Studies, NHSBT
Jane Nuttall (JNu)	Recipient Co-Ordinator, Wythenshawe Hospital
Nicky Ramsey (NR)	Recipient Co-Ordinator, Harefield Hospital
Rachel Rowson (RR)	Deputising for Marian Ryan (Regional Managers Rep), SNOD
Sally Rushton (SR)	Senior Statistician, NHSBT
Helen Spencer (HS)	Centre Director, Lung Surgeon, Great Ormond Street Hospital
Deborah Thomas (DT)	Deputised for Jas Parmar, Lung Physician, Royal Papworth Hospital
Richard Thompson	Respiratory Physician, Queen Elizabeth Hospital
Sarah Watson (SW)	Highly Specialised Services, NHS England
Craig Wheelans (CW)	National Services Division, NHS Scotland

IN ATTENDANCE:

Lucy Newman (LN)	Secretary, NHSBT
Gill Hardman (GH)	CTAG Clinical Audit Group Cardiothoracic Fellow, Freeman Hospital

Item		Action
	Apologies and welcome Apologies were received from Anthony Clarkson, Catherine Coyle, Ben Davies, Melissa D'Mello, Debbie Macklam, Karen Redmond, Andre Simon, Mick Stokes, John Richardson, Katie Morley, Rob Graham, Jas Parmar, Julie Whitney.	
1	**CTAGL(19)24 – Declarations of interest** There were no declarations of interest at the meeting.	
Please note that it is the policy of NHSBT to publish all papers on the 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 should indicate whether their paper falls into these categories		
2 **2.1** **2.2**	**CTAGl(M)(19)01 – Minutes of the CTAGL Meeting on 20/03/19** **Accuracy** The minutes were accepted and ratified as an accurate record of the last meeting. **CTAGH(AP)(19)01 – Action Points** **AP7** there were no clinical incidents reported for any form discrepancies between retrieving and recipient surgeons**.** **AP10** regarding EQ5D Quality of Life recording will be reported during item 8.5 of this meeting	
3 **3.1**	**Associate Medical Director's Report** **Developments in NHSBT** Lung Summit is taking place on 31st October to address concerns over the decrease in the number of lung transplants last year. Stakeholders invited to participate are Cardiothoracic Teams, Patient Representatives, Commissioners and Members of the Departments of Health.	

	NHSE are in the process of finalising the publication of their policy on funding for the treatment of Hepatitis C following the transplant of HCV positive donor organs. Centres with local hepatology units have agreed to start consenting patients to potentially receive HCV positive organs in line with published guidelines. A Elsharkawy (AE) (Consultant Hepatologist in Birmingham) is responsible for implementation and monitoring progress. Centres should contact AE for clarification of the acceptance process to ensure they are consenting patients appropriately. Centres will also need to develop their protocols for care of these patients in conjunction with a hepatologist with an interest locally. NHSE is in process of publishing its policy regarding funding of treatment and will advise NHSBT when this has been completed. Wales and Scotland alreadyfund treatment. It would be reasonable to start the process of patient consent while waiting for NHSE funding. The Welsh consent forms will be made available for adaptation by Trusts. European Organ Donation Day (EODD) involving the Council of Europe is being hosted by the UK in London on Saturday 12th October. Focus this year will be on DCD organ donation, technology, and organ donation from underrepresented communities. RR advised that centres will be emailed with joining instructions and will need to register their place at the EODD.	
3.2	**New appointments** J Whitney has taken over from Jackie Newby in running ODT Hub Operations.	
3.3	**Organs declined for logistical reasons** DM raised that organs offered for named patients but declined for logistical reasons should be reported to patients under the duty of candour. This has been previously discussed with the multiple Patient Groups and the general feedback was that patients felt they would like to be informed should a named offer have to be declined for logistical reasons. All patients will be asked if they would like to be given this information, and those that do will be surveyed to find out how the conversations between themselves and clinicians went. This is being piloted in the kidney population before rolling it out other groups. There is a need for consistency among centres with definition of logistical reasons for declining deceased donor organs for named patients. Logistical declines happen in all deceased donor offering. Following discussion during CTAGH, Andre Simon agreed to work on the logistical decline definitions to circulate to centres and agree within CTAGH and CTAGL so that once the process is working in kidney it can be incorporated into cardiothoracic practice.	
4	**Governance Issues**	
4.1	**Non-compliance with Lung Allocation** There were no recorded incidents of non-compliance with lung allocation since the last meeting.	
4.2	**CTAGL(19)25 – Clinical Governance Report** Injuries reported during lung retrieval are low and there have not been any injuries or organs lost to damage reported since the last CTAGL Meeting. DM clarified that when an incident is raised, the person who raised it, the clinical lead and the person named at NHSBT will receive responses, and this information should be disseminated within the centre to the whole team. The incident reporting process will be reviewed by DM and Richard Baker (RB) over the coming months to ensure that feedback is sent to the correct person with clinical responsibility and to the centre director. The group were asked for clarification of a situation in which DCD lungs are turned down for transplant but accepted for research; would an anaesthetist be required? DM confirmed that it would be the responsibility of the team requiring the donor lungs to provide the anaesthetist. DM will investigate any current research projects requiring DCD lungs and confirm as any research projects of this nature would have prior agreement at RINTAG.	
4.3	**CTAGL(19)26 – CUSUM Monitoring of 90-day outcomes following lung transplantation** There have been no CUSUM signals in lung transplantation in the last six months.	
4.4	**Group 2 Transplants** There have been no group 2 transplants since the last meeting.	
5	**Lung Allocation**	
5.1	**CTAGL(19)27 – Review of Lung Allocation Zones**	

	The report on lung allocation zones was circulated for annual review. Table 1 in the report relates to registration activity and uses data from 01/08/17 to 31/07/19 and finds that the size of the allocation zones for lung transplantation are appropriate to the number pf patients registered on the waiting list in each centre. Since the last alterations to the zones in January 2018, there have been 1463 adult DBD donors; of these, 967 had lungs offered, 517 were accepted, 235 retrieved and 218 transplanted, leading to an overall utilisation rate of 23% which was variable across zones. There were no significant differences between the proportion of patients registered on the waiting list and the proportion of donor lungs for any centre, so no alterations will be made to the Lung Allocation Zones at this stage. At present there is a requirement for the difference between registrations and allocations to be statistically significant at the 5% level, after adjusting for multiple testing, before a review of allocation zones is triggered. This may need reviewing, however there should be a balance between being sensitive to changes and not adjusting too frequently. ***ACTION: In line with the action taken from CTAGH SR will review the methodology.***	**SR**
	Cardiothoracic retrieval and transplant decision making can take excessive time and causes some delays to the retrieval of other organs, this will be discussed in more detail at the Retrieval Advisory Group next week.	
5.2	**Lung Allocation Sub-Group (LASG)** Since the last CTAGL Meeting the LASG held a telecon to gauge appetite for change to the SULAS and ULAS criteria following their introduction. The group agreed that the new schemes have not yet been running for long enough to determine whether there is a need to change the listing criteria for patients. MAA and SR, along with a lung representative from each centre, are conducting a formal review of the first 20 months of the schemes which is intended for publication. MAA has also been able to access data held on Cystic Fibrosis and Lung Fibrosis patients with a view to modelling survival data and refining the urgency criteria for these patient groups to ensure that those patients with the worst prognosis without transplant but a reasonable post-transplant prognosis are prioritised.	
5.2.1	**Super-Urgent Heart-Lung** CTAG members had been asked to re-consider the need for a Super-Urgent Heart-Lung category. The group agreed that patients receiving Super-Urgent Heart-Lungs would have less favourable outcomes as they will have been receiving mechanical support prior to listing for transplant. Although numbers are small, a report presented under Item 7.2 of the agenda, shows that the post-transplant survival of a recent cohort was lower than for lung only or heart only transplant. The consensus is that urgent heart-lung appeals should continue to be reviewed by the CTAG Adjudication Panel but there was no appetite for super-urgent heart-lung listing at present, in part due to the high waiting list mortality on the lung only list and the scarcity of suitable organs for transplant.	
5.2.2	**Lung-Liver Transplantation** An informal Lung-Liver group involving QEH, Freeman and Royal Papworth has been running for about five years, with centres sharing information on Lung-Liver patients. There have been only two Lung-Liver transplants in the past five years but there has been a recent increase in patients referred. It was previously agreed at CTAG in April 2018 that patients requiring Lung-Liver transplants may be automatically registered to the Urgent Lung Allocation Scheme. At the request of some members this decision was revisited. Some members felt that this group should continue to get access to Urgent Lung listing because of the inherent risk in the combined procedure and the need to carry out the transplant before the patient deteriorated to the point where risk was further increased. A majority decision was made that the process for listing patients for urgent Lung-Liver transplants would revert back to needing approval from the CTAG Adjudication Panel if they do not meet criteria for the ULAS. The decision of the panel in relation to Lung-Liver patients should be monitored at CTAGL. ***ACTION: SR to ensure the decisions of the panel in relation to Lung-Liver patients are reported at CTAGL in Autumn 2020***. Patients already listed will retain their current listing status and new patients will be individually reviewed by the Panel.	**SR**
5.3	**CTAGH(19)28 – Summary of Adjudication Panel Appeals** The report on adjudication panel appeals highlights that between 18/05/17 and 31/07/19 there were 16 applications for urgent adult lung registrations, of which 9 (56.3%) were approved. There were 7 appeals for urgent paediatric lung registrations, all of which (100%) were approved. This represents less than 10% of all urgent lung registrations, with the rest meeting standard urgent listing criteria. 14 (63.6%) of 22 applications for urgent heart/lung registration between 26/10/16 and 31/07/19 were approved.	

5.3.1	**Adjudication Panel Membership** JyP thanked Adjudication Panel Members for their continued support. Centres must let JyP know if they wish to change their representative on the adjudication panel.	
5.4	**Lung Transplantation for different diagnostic groups** The annual report for 2018-19 shows that the distribution of diagnostic groups differs between centres. This may be due to differences in referrals or to centres prioritising one group over another. There are differences in survival between different groups and this may influence the decision to offer transplantation. Centres should be honest with those patients on the waiting list and be able to justify their practice if questioned by champions for one or other diagnostic group.	
5.5	**CTAGL(19)29 – Paediatric donor lungs accepted for adult patients** The results of paediatric donor lung offers are being monitored while NHSBT works on an IT fix to the Lung Allocation Sequence to ensure that paediatric centres get first refusal of paediatric donor lungs. Between 01/04/2018 and 31/08/2019 there were 42 paediatric donors where the lungs were offered, resulting in 12 transplants detailed in the report attached. The monitoring has found that no paediatric patients were disadvantaged.	
5.6	**CTAGL(19)30, CTAGL(19)31 – Lung Selection and Allocation Policies** There was discussion within the group about the proposed changes to the lung selection and lung allocation policies, the changes are highlighted in the attached documents and will be approved by TPRC prior to publication. Changes to the allocation policy include removal of the non-urgent small adult patient category and the allocation of paediatric donor lungs to paediatric patients in all tiers before super-urgent adults and small adults. With the removal of the non-urgent small adult tier, the allocation sequence will be simplified which will allow for sequential offering to be resumed rather than Group Offering. However, for donor lungs that are unlikely to be accepted there should be a trigger to Group Offer them to speed up the process. The proposal is to Group Offer lungs that have been declined by three or more centres due to poor function or donor history. In these instances, a simultaneous message will be sent to the remaining centres giving them 45 minutes to respond if they would like to accept the offer, at which point the lungs will be allocated according to the sequence. It has also been proposed that lungs that have already been removed at the point of decline should not be offered on by Fast Track, however it was felt that this should continue as centres may be relaxed about ischaemia times. Minor changes have been made to the lung selection policy including adding Category 93 for listing patients on the SULAS who fall outside the criteria for listing. Other amendments to be made include final decisions about registering patients who require a combined lung liver transplant. Vaping was discussed (8.1 substance abuse) and clinicians confirmed that they ask patients about vaping as an indication of addictive behaviour. ***ACTION: SR will update the policy sections about lung liver transplants and the policy will be submitted to TPRC for further approval*.** However, the new policies will not be published until the necessary forthcoming IT changes to the allocation sequence have been made (estimated to be in the new year).	**SR**
5.7	**Update on guidelines for testing and interpreting anti-HLA antibodies** PB reported that the guidelines for testing and interpreting anti-HLA antibodies are under review as part of a UK Histocompatibility & Immunogenetics Laboratories Audit. Separate guidelines may be required for heart and lung transplantation.	
6 6.1	**ODT Hub Update** **Organ offering changes and Fast Track triggers** JW was unable to attend CTAGL but at CTAGH it was reported that JW conducted a review within ODT Hub; identified issues all fall within 16 main themes. One over-arching piece of work surrounds messaging to centres with offers. Recipient Points of Contact (RPOCs) are using different and sometimes unreliable methods for receiving organ offers which causes delays and potential missed opportunities as not all relevant contacts receive the messages of offers in a timely fashion. Workshops are planned to find solutions to issues identified in the review. Quick fixes will be changing contact protocols, changing triggers for Group Offering and no re-offering to centres which have previously declined the same offer for all recipients.	
7 7.1	**Statistics and Clinical Studies reports** **CTAGL(19)32 – Summary from Statistics and Clinical Studies**	

	Since the last meeting the Statistics and Clinical Studies team have published the Annual Transplant Activity Report as well as the Organ Specific Annual Reports. Infographics to accompany the Activity Reports are in development. Overall findings are that there are more donors but fewer transplants, particularly within cardiothoracic transplant. An NHSBT and BTS joint Lung Summit is scheduled for 31st October to address the concerns in lung transplantation numbers, Statistics and Clinical Studies will be preparing a presentation for the meeting. SR will be going on Maternity Leave in November 2019, LM will support Cardiothoracic Transplantation while SR is on leave. GH (NHSBT Cardiothoracic Clinical Audit Research Fellow) will be continuing the ideal lung donor work that SR and John Dark have previously been involved with. Collaborative work with the Winton Centre is ongoing to develop a communication tool to communicate risk and consent for transplant patients. The tool will be rolled out to Lung Patients first, followed by Kidney and then Heart patients.	
7.2	**CTAGL(19)33 – Summary of Heart-Lung Transplants** Reported under item 5.2.1.	
8	**Reports and Discussion Points from the Chair**	
8.1	**CTAGL(19)34 – CT Centre Directors Telecon key discussion points** The minutes from the last Centre Directors Telecon on 26th July 2019 are attached for information.	
8.1.1	**CTAGL(19)35 – Grading of retrieved Cardiothoracic Organs** In January 2017, a data collection pilot was set up for centres to complete and return organ grading forms for all retrieved cardiothoracic organs; one at retrieval and one at transplant. This is a final report as data collection has now ceased, as agreed at the last Centre Directors' teleconference. The average overall form return rate for lungs was 74.3% from retrieval surgeons and 67.2% from recipient surgeons. The national damage rate for retrieved lungs was 2.8% when reported by retrieval surgeons and 4.5% when reported by recipient surgeons (lower than for hearts). When comparing damage rates for organs retrieved by the same team as the accepting centre or a different team, however, the rates were very different, at 0.9% and 6.3% respectively. This highlights subjectivity in damage reporting. Centre Directors agreed to halt this data collection as the grading will be built into the digital HTA-A and HTA-B Forms when they are released. When compared to other organs, cardiothoracic organs appear to incur less damage than abdominal organs. For pancreases in particular, reported damage is much higher. The Retrieval Advisory Group are trying to devise a CUSUM to monitor damaged organs on a national and local level.	
8.1.2	**CTAGL(19)36 – Registry Form Returns** CTAG has been trying to resolve issues with Registry Form Return Rates, some centres have a number of these forms outstanding which results in outcome data being skewed. This has been discussed at CTCAG and the recent Centre Directors Telecon where it was agreed that if centres are unable to provide a minimum of 70% of Registry Forms, their data will be removed from the funnel plot analysis in the next Cardiothoracic Transplant Activity Report. Most CTAG Members support a financial penalty for centres that continue to show poor return rates and recommend that NHSE builds this into contracts. ***ACTION: SR will notify centres (copying in SW) around April 2020 of their form return rates ahead of the next Annual Report on Cardiothoracic Transplantation.***	**SR**
8.2	**RAG (NRG) Update** The Clinical Retrieval Forum and NRG were overlapping in streams of work so the two groups were consolidated to form the Retrieval Advisory Group (RAG) which will be co-chaired by Marius Berman and Ian Currie since they started as Associate Clinical Leads for Organ retrieval in April 2019. RAG will include 16 NORS Leads, Lay Members, Clinical Commissioning Members, Clinicians etc… the first official RAG Meeting is scheduled to take place on 1st October.	
8.3	**Recording QOL following transplant**	

	Measuring Quality of Life (QoL) in patients pre and post-transplant is an important step in improving treatment by broadly identifying QoL markers to measure and identify deficiencies in order to target improvements in allocation, treatment and care to improve patient outcomes. To add value, QoL data would need to be included when reporting on outcomes from cardiothoracic transplants. An allocation algorithm could incorporate waiting list mortality, transplant benefit and potential for improved quality of life. Internationally, there is no precedence for using QoL in allocation; the Lung Allocation Score in the US weights waiting list mortality twice as heavily as post-transplant survival. NHSBT does not have the staff to collect this information centrally at present. MC asked whether this could be added to the CTAG Workstream, although to implement the collection would involve IT changes. ***ACTION: MC will discuss further with ALTP colleagues to decide on the appropriate tools for recording QoL data, and will then speak with LM to determine how to move this process forward.***	**MC**
8.4	**VV-ECMO for Super Urgent Lung Patients** Since the last CTAGL Meeting the clinical panel have completed the impact assessment and this is now out for consultation. The next steps are to write the report and respond to queries raised by NHSE.	
8.5	**CTAGL(19)37 – QUOD Update** The QUOD Biobank was established in 2012 and since then has supported 55 projects and currently holds over 80 BAL samples. CTAG are reminded that recipients do need to be suitably consented before receiving an organ which has been subjected to QUOD Biopsy. Further work is needed to investigate the legal and ethical risks of receiving a biopsied organ and to ensure the QUOD Biobank remains active.	
9	**Reports from sub-groups**	
9.1	**CTAGL(19)38 – CTAG Clinical Audit Group (CAG) Chairs Report** The CTAG Clinical Audit Group Report was presented by MAA. Work is underway to review the risk models used by NHSBT in the annual audit reports. Stephen Pettit is leading this from the heart side. The membership of the group has expanded, with the current NHSBT clinical research fellow now being a formal member, having not been previously in recent years.	
9.1.1	**CTAG Clinical Audit Group Vacancies and Appointments** The position of MCS Representative will become vacant in December 2019. The current incumbent, Dr Steve Shaw is welcome to stand for re-election. Requests for expressions of interest in the role of MCS representative will be circulated in October 2019.	
9.2	**CTAGL(19)39 – CTAG Patient Group** The CTAG Patient Group Minutes are attached, members of the group are proactive and participate fully and actively at patient meetings, offering valuable patient feedback. The patient group meeting in May 2019 included at least one patient representative from each of the 7 cardiothoracic transplant centres and was the best attended meeting on record with over 30 participants in attendance.	
9.3	**Single Lung Transplant Outcomes** A request has come to report the outcomes of single lung transplants separately to bilateral lungs in the annual report. The Audit Group is considering how best to report this data.	
10	**Lung Utilisation**	
10.1	**CTAGL(19)40 – Centre Specific Activity Report (first five months)** The Centre Specific Activity Report identified that 78 lungs were used for transplant in the first five months of this year while 61 lungs were used for transplant in the same time period last year. Lung transplant activity was 22% lower in 2018/2019 when compared with 2017/18, however, activity has now increased by 28% when compared to the same five-month period from 2018/19.	
11	**CTAGL(19)41 – Birmingham Lung Review shared learnings review** The outcome of the Birmingham Lung Review was circulated in advance of this meeting in order that there was shared learning. The review was carried out when routine monitoring of lung transplant outcomes at 90 days and 1 year indicated higher mortality rates than at other UK centres. The differences were highlighted in NHSBT Annual reports (2017/18, 2016/17 and 2015/16) and in CUSUM mortality triggers in 2018. Outcome data was analysed by the NHSBT Statistics and Clinical Studies Team using standard methodology.	

	JM and RT commented that the review had been useful and interesting, JM grateful for the time and expert advice provided during the review. As soon as the CUSUM Signal was flagged at QEH, an internal review of all patients took place immediately. Moving forward, QEH will implement several improvements: • Using ECMO rather than Cardiopulmonary bypass for lung transplant procedures • improvements in the pre-operative regime • utilising the skills of the thoracic surgical/anaesthetic team from a neighbouring hospital • improved access to rehabilitative physiotherapy • improved psychological support to pre-transplant patients. These and other points are listed on page 5 of the attached report. Members are welcome to email RT/JM with any questions or for any further information.	
12 **12.1** **12.2**	**For Information** **CTAGL(19)42 – Transplant Activity Report** For information only, no comments raised. **CTAGL(19)43 – NHSBT ICT Update for Advisory Groups** For information only, no comments raised.	
13	**Any other business** MC has submitted a funding application to fund ECP as treatment for Chronic Lung Allograft Disfunction Transplantation data has been provided to Public Health England's Respiratory Atlas of Variation which has been published today. RT expressed thanks on behalf of the group to SR for her help and support, and the group wishes SR well for her upcoming Maternity leave.	
Date of next meetings **CTAG Patient Group – Wednesday 13th November 2019 – 1230-1600** **Coram, 41 Brunswick Square, London, WC1N 1AZ (Sandwich Lunch 1200-1230)**		