NHS BLOOD AND TRANSPLANT
ORGAN DONATION AND TRANSPLANTATION DIRECTORATE

THE SIXTEENTH MEETING OF THE NHSBT CTAG HEARTS ADVISORY GROUP ON MONDAY 28 SEPTEMBER 2020 11:00-16:00 VIA MICROSOFT TEAMS

MINUTES

Attendees:

Jayan Parameshwar (Chair)	JP	CTAG Hearts and Lungs Chair, Royal Papworth Hospital
Ayesha Ali	AA	Highly Specialised Services, NHS England
Lynne Ayton	LA	Transplant Managers Forum Representative
Jenni Banks	JB	Statistics & Clinical Studies, NHSBT
Marius Berman	MBe	Joint Associate Clinical Lead Organ Retrieval, NHSBT, Cardiac Surgeon, Royal Papworth Hospital
Mike Burch	MBu	Paediatric Cardiologist, Great Ormond Street Hospital
Ian Currie	IC	National Clinical Lead for Organ Retrieval, NHSBT
Phil Curry	PC	Cardiac Surgeon, Golden Jubilee National Hospital
John Dark	JDar	University of Newcastle (invited)
Jonathan Dalzell	JDal	Centre Director, Cardiologist, Golden Jubilee National Hospital
Matthew Fenton	MF	Centre Director, Paediatric Cardiologist, Great Ormond Street Hospital
John Forsythe	JF	Medical Director, OTDT, NHSBT
Margaret Harrison	MH	CTAG Lay Member Representative
Emma Johnson	EJ	CTAG Patient Group Member, Advocate of Max and Keira's Law
Sern Lim	SL	Cardiologist, Queen Elizabeth Hospital, Birmingham
Guy MacGowan	GMG	Cardiologist, Freeman Hospital
Derek Manas	DM	Joint Clinical Governance Lead, NHSBT
Lisa Mumford	LM	Head of ODT Studies, NHSBT
Stephen Pettit	SP	Centre Director, Cardiologist, Royal Papworth Hospital
Tracey Rees	TR	H&I Representative, The Welsh Blood Service
Fernando Riesgo-Gil	FRG	Cardiologist, Harefield Hospital
Sally Rushton	SR	Senior Statistician, NHSBT
Philip Seeley	PS	Transplant Coordinator, Freeman Hospital
Steven Shaw	SS	Cardiologist, Wythenshawe Hospital
Frederick Smith	FS	Statistician, NHSBT
Ulrich Stock	US	Centre Director, Surgeon, Harefield Hospital
Teressa Tymkewycz	TT	London SNOD Team Manager, deputising for Rachel Rowson
Rajamiyer Venkateswaren	RV	Centre Director, Surgeon, Wythenshawe Hospital
Sadie Von Joel	SVJ	Lead Nurse Recipient Coordinator, NHSBT
Sarah Watson	SW	Highly Specialised Services, NHS England
Julie Whitney	JW	Head of Service Delivery (ODT Hub), NHSBT

Apologies:
Nawwar Al-Attar, Stephen Clarke, Catherine Coyle, Ben Davies, Paul Flynn, Anushka Govias-Smith, Rob Graham, Ben Hume, Melissa D'Mello, Marian Ryan, Nicky Ramsay, Rochelle Pointon, Jeanette Foley, Sue Duncalf

In attendance:

Heather Crocombe (Minutes)	HC	Clinical Support Services, NHSBT

No.	Item	Action
	Welcome and Apologies JP welcomed everyone to today's Meeting and gave details of apologies (please see above).	

	Attendees were asked, if we are going to continue to hold CTAG Meetings virtually, should we continue to hold them at the same time (mid-morning to mid-afternoon), or eg. start them at 9am and finish by 1pm? Members to contact JP please, with their views.	**All**
1.	**Declarations of Interest in relation to the Agenda CTAGH(20)22** There were no declarations of interest in relation to today's Agenda.	
	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.	**Minutes of the CTAGH Meeting held on 23 March 2020 CTAGH(M)(20)01**	
2.1	Accuracy The Minutes of the CTAGH Meeting held on 23 March 2020 were deemed to be a true and accurate reflection of the content of that meeting.	
2.2	Action Points from the CTAGH Meeting held on 23 March 2020 **CTAGH(AP)(20)01**	
AP1	**Declining Donor Hearts on Logistic Grounds** This can now be removed from the Agenda	**HC**
AP2	**Heart Allocation Zones** This is on today's Agenda (point 8.2)	
AP3	**Heart Allocation Sub-Group** To discuss not only sensitisation, but to discuss which data should be included in the analysis of factors affecting waiting times to heart transplant, see if this can be written into an algorithm, and report back to CTAG. *Ongoing. (S Lim/S Rushton)*	**SL/SR**
AP4	**Heart Transplantation Policy Changes** On today's Agenda (point 8.4)	
AP5	**Organ Offering and Fast Track** We are trying to give full access to EOS to the ROI coordinators, in order that we can make offers to the ROI before offering to the rest of Europe. This will make improvements to the pathway between us and the ROI. *In progress, ongoing. JW to report back at next meeting*.	**JW**
AP6	**Papers from Audit Group:**	**On hold**
AP7	**Length of donation pathway** On today's Agenda (point 6.2)	**MB**
AP9	**DCD Hearts for Paediatric Patients** Completed. Remove from Agenda.	**HC**
AP10	**CTAG Work Plan** Completed. Remove from Agenda.	**HC**
3.	**Medical Director's Report**	
3.1	Developments in NHSBT	

	• Firstly, JF wanted to say thank you to the heart transplant community via the representatives on today's call. As a service we were able to continue transplantation for the most urgent patients on the transplant list during the COVID pandemic, which showed incredible teamwork. • During July 2020 (across the whole of donation and transplantation), there were 128 donors and 318 transplants performed. This was the busiest July in a decade. • From March to August 2020, 97 heart transplants were performed (of which 22 were paediatric). • The latest COVID bulletin contained a link to a second COVID surge document (https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/19870/covid-19-bulletin-22-24092020.pdf) • Local barriers to organ utilisation: Centre Leads should have received details of an initiative about organ utilisation (looking at resilience and sustainability of the service). Each centre can now appoint a senior individual to lead on utilisation; those Leads will then provide information about their centre to a central "pot", to give a fuller picture of what is common across centres and what is idiosyncratic • Collaboration with Winton Centre: We hope to able to help clinicians and patients make difficult decisions regarding transplantation. There are now many tools available electronically/digitally that allow different scenarios to be keyed in – this then produces a prediction based on past experience. *Points made*: • With Track and Trace, the number of clinical staff absent from work has increased, mostly due to children needing to isolate because of COVID cases at their schools. Centres are managing to keep going, despite staff shortages. • It can take up to 5 days for negative COVID results to come back. • Golden Jubilee unfortunately had 50% of transplant staff off the first week that schools returned (comprising staff in isolation, on annual leave, and on sick leave) so the programme needed to stand down for 12 hours • Harefield have put in place a staff rotational system to ensure that all transplant cardiologists are not in the hospital at the same time. This approach may not be appropriate in all other Centres.	
3.2	New Appointments None	
4.	**Research Proposals**	
4.1	Donor Statin Study **CTAGH(20) 23a and 23b** This Study has been formally approved today. **Please note this information is confidential.** Members viewed a presentation by J Dark (being shown at all Advisory Groups), outlining the findings from a study published by Karl Lemstrom from Helsinki in 2019. This led to the design of the SIGNET Study which is awaiting approval in October. The Helsinki Study involved 84 recipients, of whom half received organs from donors given Simvastatin and analysed the outcomes on the heart and the effect on all other organs. It was noted that there was no harm in lung recipients but may have helped improve outcome, with a halving of PGD rate. The SIGNET Study is envisaged to start in April 2021 for a period of 4 years. Donor family consent will be required for donation and research. All potential recipients will receive information about the study, with a description of the potential benefits - there is	

	unlikely to be any risk to recipients and the intervention will occur before the potential recipients have been identified so no consent will be required by recipients. No additional data or samples are required from recipients. This will be the largest donation intervention study in the world. The following were confirmed: • Simvastatin 80mg given as a single dose is a safe drug to use with no measurable amount transferred to the recipient. The delay between consent and retrieval is usually around 24 hours, so by the time the organ has been flushed and on ice, essentially no drug will be present As this Study will last for 4 years, J Dark confirmed that he would be happy for donors to take part in parallel studies (eg. PITHIA study), and there will be no problem with co-recruitment. JF congratulated J Dark for getting this study to the "green light" stage. J Dark offered to give a presentation to the CTAG Patient Group in November, and JP agreed this would be very helpful.	**Invite to be sent to JD**
4.2	Outcomes after Urgent Heart Transplants for LVAD-related Complications **CTAG(H)(20)24** *Proposed Study: Review of outcomes of urgent heart transplantation in patients with LVAD-related complications in the UK (approx. 80 patients)* SL advised that this is a retrospective review of outcome data recorded since 2016 relating to heart transplants in patients with LVAD complications. These patients would have gone on the Urgent List after approval by the Adjudication Panel. We could also look at outcomes in patients where permission for urgent listing was not granted by the Panel. SL asked attendees for their feelings on this Study, and if they support it *Discussion points:* • Any lessons we can learn from reviewing this data will be helpful • US, FRG and SP all gave their support to this project and offered their help moving forwards If anyone has any comments or questions on the Study, please contact SL directly.	
5.	**Governance Issues**	
5.1	Non-Compliance with Heart Allocation DM raised the case of a heart-liver patients who had been delisted because they had been urgent listed without permission. The patient is now back on the urgent list as Panel gave permission for this over the weekend. DM and JP to discuss Panel referrals further, offline. • JP asked if colleagues felt that all urgent heart-livers should go through Panel, as a matter of course. After discussion, this was agreed, and will need to be updated in the heart allocation policies.	**DM/JP**
5.2	Clinical Governance Report **CTAGH(20)25** CTAGH are requested to note the findings within this report, review the action request and the decision made at CTAGL	

	Key Points: • An incident occurred where an adult cardiothoracic patient was registered for an Urgent Heart as "Any ABO" donor blood group – they subsequently did not appear on Matching Runs. An investigation of this incident found that "Any ABO" blood group was a category for paediatric patients only, but the same form was used to register both adult and paediatric super-urgent and urgent heart patients. A retrospective check was carried out to ascertain if there had been other adult recipients registered as "Any ABO" since July 2017. Four recipients were identified, but it was confirmed that these recipients were not disadvantaged. Hub Operations now has a clear internal process to trigger contact with a centre if a patient is removed from the run due to an "Any ABO" registration. • A case was reported on 02.09.20 regarding a patient on the routine list for a lung-liver transplant. This was discussed at CTAGL, and the decision was made that ***"If the recipient appears on the liver matching run, Hub Operations are to offer to the lung-Liver patient after all urgent offering and before group offering (for all cases)" A similar approach was suggested for heart-liver patients and will be considered at this meeting.*** • DM stressed that communication between abdominal and cardiothoracic teams is very important, and we need to keep working on communication between senior medical staff (rather than relying on junior staff), particularly where timings for retrievals are concerned	
5.3	CUSUM Monitoring of 30-Day Outcomes following heart transplantation **CTAGH(20)26** Over the six-month period since the last Cardiothoracic Advisory Group Meeting, there has been one signal reported in the CUSUM monitoring 30-day mortality following heart transplantation (relating to a transplant carried out at Harefield Hospital in April 2020). This is being investigated, and the outcome is awaited. The baseline for CUSUM monitoring is being changed – Statistics and Clinical Studies, NHSBT, will present on these baseline changes at the next CTAGH Meeting in spring 2021.	
5.4	Group 2 Transplants There have been no Group 2 Transplants	
6.	**ODT Hub Update**	
6.1	Changes to offering process • JW advised that the "single point of contact for all named patient" offers went live today • JW expressed her thanks to all Centres for their help in getting this up and running • A few other small tweaks have been made to the offering process, in terms of making sure Hub Operations pulls in all mandatory data required before offering. • During COVID some changes to offering were made – offers were made simultaneously to the top three centres for all the patients on their lists, asking those Centres to consider all their patients. This worked well during COVID but is harder to use now as the number of donors has increased. *QU: JP asked if all the offering changes that have been made are now included in the allocation system document for hearts and lungs?* JW will check with LM if these changes have been made, or if we are holding off.	**JW/LM**
6.2	Length of Donation Pathway and Recommendations *Mandatory Dataset*	

	Most of the delays in the offering sequence are because of inaccurate or missing information. MB presented a list of mandatory data required before offering: • Regarding lungs, to have a chest x-ray within 24 hours of offering • Blood gases on 100% within 2 hours of offering • Regarding hearts, a chest x-ray and ECG within 24 hours of offering • An Echo would be the gold standard for both DBD and DCD hearts but will not be mandatory in order to mobilise a retrieval team. In an ideal world, it would be best to have a good Echo before retrieval teams are despatched. After discussion, members agreed that in the case of a DCD heart, they would still require an Echo before any action is taken. *Points made:* • There seems to be a lack of understanding from some SNODs as to the minimum dataset required. Educating current and new SNODs would be very useful • A checklist that SNODs will need to complete before they can move onto the donation pathway is being prepared (*Do you have gases that are less than 24 hours old? Do you have a chest x-ray which is less than 24 hours old*)? • Significant delays in the donation pathway are sometimes caused by lack of an Echo. If we can't get an Echo but we can get FICE, it may be worth considering. Sern Lim pointed out that FICE was not intended to study cardiac structure and was therefore inadequate as a technique in this setting. • SVJ thanked MB and JW for all their hard work on this minimum dataset	
6.3	<u>Update on Heart/Lung Offering Scheme Changes</u> The changes listed below are coming into force on 13/14 October 2020 • A super-urgent paediatric tier is being added to hearts • We are allowing large paediatric patients requiring super-urgent or urgent listing to be registered with an adult status • We are releasing electronic versions of registrations forms. These can be completed online and emailed to Hub Operations	
7.	**DCD Hearts** • The national DCD hearts scheme now up and running, few teething problems but so far so good • One successful retrieval last week • Two hearts done under this scheme so far	
8.	**Heart Allocation**	
8.1	<u>Summary of Adjudication Panel Appeals</u> **CTAGH(20)27** This paper covers adjudication panel referrals 26 October 2016 - 31 August 2020 and is provided for information and to monitor the number of Adjudication Panel referrals (and approval rates). Patients are referred to the CTAG Heart Adjudication Panel when they do not meet the standard listing criteria for urgent or super-urgent heart transplant listing. <u>Key Points</u> • *Between 26 October 2016 and 31 August 2020, there were 99 adult referrals and 23 paediatric referrals to the Heart Adjudication Panel for urgent or super-urgent listing*	

	• *Of the 99 adult appeals, 82 were for urgent listing and 17 for super-urgent listing with approval rates of 82.9% and 47.1% respectively. All but one of the paediatric appeals were approved* • *Of the 82 urgent adult appeals, 64 (78%) of the recipients had a long-term VAD implanted at the time of application. Within the time period, Harefield had the highest number of urgent adult appeals and had the highest number of urgent registrations* • *For the super-urgent adult appeals, 8 (47%) of the 17 cases had a long-term VAD implanted at the time of application and again, Harefield had the most registrations over this period. 4 of the paediatric heart patients had a long-term VAD at the time of appeal, 1 from Newcastle and 3 from Great Ormond Street* • *During the same time period, 27 appeals were made for heart-lung listing, 22 of which were for urgent listing and 5 for super-urgent listing. Of these 27, 19 (70.4%) were approved. Harefield had the highest number of heart-lung appeals and the highest number of urgent heart-lung registrations* JP wanted to say thank you to all the members of the Panel who volunteer their time and deal with these cases in a timely manner. Matthew Fenton is joining the panel as of today, replacing Ben Davies	
8.2	<u>Review of Allocation Zones</u> **CTAGH(20)28** Please see paper for full details. Key points: • The cardiothoracic allocation zones were split into separate heart and lung allocation zones over two phases, in May 2017 and January 2018 • This report is the third annual review of the heart allocation zones since these changes • The report provides up to date figures on each centre's percentage share of registrations onto the national heart transplant list, for the two-year period 1 August 2018 – 31 July 2020. It also provides numbers of heart donors over the three-year period 1 August 2017 – 31 July 2020 under the current allocation zones implemented 8 January 2018 • When comparing the proportion of heart registrations made by each centre with the proportion of heart donors in each of the current heart allocation zones as implemented on 8 January 2018, there were no significant differences observed. Therefore, there is no evidence for a change in the zones at this time. *Qu: We are using statistical methodology to look at heart registrations and donors within a particular zone to decide whether boundaries change. What sort of magnitude of difference between heart registrations and donors in the current zones will be required to influence the P Value?* FS couldn't advise the magnitude of difference that would be required. LM confirmed that this will be looked at in greater detail. *Points made:* • The problem is with the ranges for height and weight, this is gender dependent (ie you may be willing to accept a size mismatch if going male to male, but not if female to male) • Why do the numbers of offers differ so much between Centres (some receive double the offers despite having a similar number of urgent and super-urgent patients listed)? Statistics investigated this situation and found that Harefield received more patient-specific offers than all other centres – this will be a contributory factor. For example, 1 patient alone at Harefield had received 47 offers, most of which were declined. • Harefield declines a lot of hearts based on size and HLA mismatch. Harefield may have a cohort of patients who are highly sensitised and on the Urgent list.	**LM/FS**

	• Should the UK be moving towards heart mass-based sizing? Receiving offers based on heart mass would involve a huge amount of IT system change and would take some time, but is something to work towards, if all Centres agree • JP advised that a Working Group will need to be set up to look at this process, and he will set up a group after this meeting.	**JP**
8.3	Heart-Liver Update *Qu. Can we look at heart-liver numbers each year – that data would be very useful.* LM confirmed that this can be done.	
8.4	Policies for Review Organ Allocation Policy Please see paper for full details. Key changes: • The ability has been added for a large paediatric patient to be registered on the urgent or super-urgent adult list • Introduction of a super-urgent paediatric and small adult tier • Section added on combined heart and abdominal allocation • Description of new offering process without automatic group offering after urgent and super-urgent offering, but instead triggered by three declines for poor function or donor history • Fast track offers no longer first-come-first-served but considering the offering sequence • Introduction of DCD Heart Allocation Patient Selection Policy Please see paper for full details. Key changes: • Introduced the ability for a large paediatric patient to be registered on the urgent or super-urgent adult heart list • Introduction of a super-urgent paediatric and small adult tier • Clarification on heart-lung listings, patients requiring combined heart and liver transplantation, and Adjudication Panel approval	
9.	**Statistics and Clinical Studies reports**	
9.1	Summary from Statistics and Clinical Studies – Autumn 2020 **CTAGH(20)30** This paper provides an update from Statistics and Clinical Studies and summarises recent presentations, publications, and current and future work in the area of cardiothoracic transplantation. Key Points: • New and updated reports, all Advisory Group papers and conference presentations continue to be posted on the ODT Clinical Site (www.odt.nhs.uk) The following reports have been published on the ODT Clinical Site and circulated to cardiothoracic centres and commissioners since the last CTAG meeting: • The 2019/20 Annual Report on Cardiothoracic Transplantation; and • The 2019/20 Annual Report on Mechanical Circulatory Support Related to Heart Transplantation • A presentation was given on lung donation and transplantation in the opening plenary of the British Transplantation Society Conference 4-6 March 2020. The slides are available here https://www.odt.nhs.uk/statistics-and-reports/slides-and-presentations • A paper was published on the super-urgent heart allocation scheme in the Journal of Heart and Lung Transplantation:	

	Rushton S, Parameshwar J, Lim S, Dar O, Callan P, Al-Attar N, Tsui S, MacGowan GA. The introduction of a super-urgent heart allocation scheme in the UK, a 2-year review. The Journal of heart and lung transplantation : the official publication of the International Society for Heart Transplantation 2020 Jun 20;S1053-2498(20)31614-4. doi: 10.1016/j.healun.2020.06.013 **Please see CTAGH(20)30 for Current and Future Work.**	
9.2	COVID-19 Update **CTAGH(20)31** *Key Points:* • The number of deceased donor transplants fell from 80 performed in one week at the beginning of March 2020 to just 8 at the end of March 2020 • Deceased donor transplants have since been steadily increasing with 79 performed in the w/c 31 August 2020 • 845 of the 56,821 recipients with a functioning graft are reported as testing positive for SARS-CoV-2. Of these, 26% are reported to have died as at 16 September 2020 • The infection rate across England ranges from 0.8 in the South West to 2.9% in London in recipients with a functioning graft • 233 of the 6136 patients on the active waiting list at 1 February 2020 are reported as testing positive for SARS-CoV-2. Of these, 11% are reported as having died at 16 September 2020 • The infection rate across England ranges from 0.7% in the South West to 8.3% in London, for patients on the active waiting list • Of the 2468 transplants performed so far in 2020, 81 recipients have tested positive for SARS-CoV-2 with 10 reported as having died	
10.	**Reports and Discussion Points from the Chair**	
10.1	Recovery Planning Recovery planning documents are now available on the NHSBT ODT website	
10.2	COVID-19 second wave planning COVID-19 second wave planning documents are now available on the NHSBT ODT website	
10.3	RAG (NRG) Update • SherpaPak. SherpaPak is essentially a cool box to transfer hearts. The biggest advantage is that hearts are stored in saline with cooling pouches. The latest consensus is that it might have advantages for users in the UK. The six heart centres in the UK are very keen to try SherpaPak. NHSBT are willing to facilitate this, so long as NORS teams are carrying out retrievals. • The manufacturing company, Paragonix, provided some SherpaPak free of charge but the exact cost needs to be explored. • MB will circulate a SherpaPak paper to CTAGH members, to provide further information • JW and MB will have a conversation offline about this • There was a national randomised study originally mentioned by MB at CTAGH some time ago (*St Thomas's vs. Custadiol*) An NHSBT research fellow has now been appointed who will start work in February 2021. MB will circulate details and a full Protocol when ready. MB would welcome collaboration from all centres.	**MB** **MB/JW** **MB**

	• Smart Glasses with a microphone to be used by retrieval fellows to communicate live streaming of organ assessment, which will be interactive. MB advised that funding has been secured from the Papworth Charity, and hopefully a 6-month pilot will start in the next month or two. US asked if he can apply for similar funding from the Harefield Charity to support Papworth? MB will send full details to US, and yes, MB would be delighted if Harefield is able to join.	**MB**
10.4	QUOD Update **CTAGH(20)32** QUOD Bioresource key figures: • Donors – 4,913 • Samples – 88,920 in total, comprising: • 46,327 blood samples • 10,769 urine samples • 12,375 kidney samples (6,268 biopsies) • 6,539 liver samples (3,285 biopsies) • 7,153 ureter samples (3,607 biopsies) • 3,666 spleen samples (3,666 biopsies) • 133 BAL samples • 1,958 heart samples (984 biopsies)	
11.	**Reports from Sub-Groups**	
11.1	CTAG Clinical Audit Group (CAG) Chairs Report **CTAGH(20)33** Please see paper for full details • There is one post becoming vacant in the next two months (Donor Management and Organ Retrieval Representative) so JP will be calling for people to apply • There was a request for an H&I Representative, and Tracey Rees confirmed that she would be happy to cover this	
11.2	CTAG Patient Group **CTAGH(20)34a and 34b** Please see paper for full details • Patient Group has met twice since the last CTAGH Meeting – an extra meeting because of the COVID-19 outbreak • Ongoing anxieties for patients and their families	
12.	**For Information**	
12.1	Transplant Activity Report – see paper for details, or go to the following page: https://www.odt.nhs.uk/statistics-and-reports/annual-activity-report/ **CTAGH(20)35**	
12.2	NHSBT ICT Update for Advisory Groups **CTAGH(20)36** See paper for details and information	
13.	**Any Other Business** FRG mentioned a possible study that Harefield might take on, if a similar study has not been carried out already. Harefield have had 3 or 4 patients with very early PTLD after being EBV mismatched. They plan to look into whether we should include that as a factor when deciding about induction therapy.	**FRG**

	FRG will send details of this study to other centres, to see if they would like to participate.	
	Date of next meeting: Monday 22 March 2021 - 11:00-16:00 We will decide whether this meeting will be in person or virtual, and whether we wish to have an earlier start and finish the meeting over the course of the morning.	