## Apologies and welcome

Apologies were received from Catherin Coyle, Melissa D’Mello, Jonathan Dalzell, Margaret Harrison, Ben Hume, Debbie Macklam, John Richardson, Mick Stokes.

## Action

There were no relevant declarations of interest at the meeting.

### CTAGH(M)(19)01 – Minutes of the CTAGH Meeting on 28/03/19

**Accuracy**

LN to make minor corrections to attendees of the previous meeting which can then be accepted as an accurate record of the last meeting.

### CTAGH(AP)(19)01 – Action Points
Action points raised from the last meeting were completed on or before this meeting. The one action point to remain open and ongoing is the need for forms to be completed and returned to NHSBT to monitor long term outcomes for heart transplantation recipients.

### 3

**3.1 Associate Medical Director’s Report**

**Developments in NHSBT**

JF thanked the group for their collaboration with NHSBT over the Joint Innovation Funding bid for DCD Heart Transplantation which demonstrated unity of purpose, belief in the technology and a willingness to develop DCD Heart Transplantation further.

Transplantation of HCV positive organs to HCV negative recipients has been discussed previously, A Elsharkawy (AE) (Consultant Hepatologist in Birmingham) is responsible for implementation and monitoring progress. Centres should contact AE for clarity of the acceptance criteria and to ensure that 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 on this and will advise NHSBT when this has been completed. Wales and Scotland already have their policies published. It would be reasonable to start the process of patient consent while waiting for NHSE confirmation of funding. The Welsh consent forms will be made available for adaptation by Trusts.

Lung transplant figures were approximately 20% lower last year and JF is very concerned about the potential shortcomings in the service. Centres are invited to send up to 10 members of their transplant teams (no more than 2 from any discipline) to attend the Lung Summit which will be attended by Cardiothoracic Teams, Patient Representatives, Commissioners and Members of the Departments of Health on 31st October to address the situation.

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.

NHSBT Board feel that if an organ is offered to a named patient but declined for logistical reasons, the patient should be informed of this decision. The scheme is being piloted in kidney transplantation from October with centres being made aware of this policy. It will be monitored and if successful, it will be rolled out to other organ groups. Patient Groups were previously asked about this and agreed that they would prefer to know if an organ offer for them is declined solely on logistical reasons. Members discussed that there are different types of lack of resource and there should be a national agreement on what constitutes a lack of resource.

**ACTION:** ASi to draft a proposal of what constitutes a lack of resource when declining a donor heart for a named patient.

**ACTION:** LN to add to agenda for next Centre Directors Teleconference and discuss again at CTAG patient group.

### 3.2 New appointments

J Whitney was formally introduced to the group having taken over from Jackie Newby in running Hub Operations.

### 4

**4.1 Non-compliance with Heart Allocation**

There were no recorded incidents of non-compliance with heart allocation since the last meeting.

**4.2 CTAGH(19)32 – Clinical Governance Report**

Open incidents are detailed in the Clinical Governance Report, the most common reason for raising incidents relating to cardiothoracic retrieval and transplant is the additional time delay caused by aspects of cardiothoracic retrieval which has a detrimental impact on the timings for the retrieval of abdominal organs. The reasons for delays include decision making on the part of the accepting centre, logistical issues and the use of OCS for DBD heart retrievals.

**ACTION:** MB will write to all cardiothoracic centres to reiterate that when they opt to send an OCS team in addition to the cardiothoracic NORS retrieval team, the use of OCS in DBD heart retrieval will only be acceptable when there is no delay caused to the retrieval process. The NORS retrieval team in attendance will lead in all aspects of the retrieval.

**ACTION:** LN to add to agenda for next Centre Directors Teleconference and discuss again at CTAG patient group.

---

**Organ Donation and Transplantation Directorate**

**September 2019**

---

**ASi**

**LN**

**MB**
4.3 **CTAGH(19)33 – CUSUM Monitoring of 30-day outcomes following heart transplantation**

Since the last meeting there has been one CUSUM signal within the 30-day monitoring period following heart transplantation at Harefield Hospital. Following an internal review; NHSBT is carrying out an external review (in November). Findings and lessons learned from the investigation will be reported to CTAG.

4.4 **Group 2 Transplants**

There have been no group 2 transplants since the last meeting.

5 **Heart Allocation**

5.1 **CTAGH(19)34 – Review of Heart Allocation Zones**

The report on heart allocation zones was circulated for annual review. Table 1 in the report relates to registration activity from 01/08/17 to 31/07/19 and donor activity from 01/08/16 to 31/07/19 and finds that the size of the allocation zones for heart transplantation are appropriate to the number of patients registered on the waiting list in each centre (no statistically significant difference). Since 8 January 2018, where the zones were last altered, there were 1463 adult DBD donors; of these, 838 donor hearts were offered, 511 accepted, 228 retrieved and 223 transplanted.

There were no significant differences between the number of patients registered on the waiting list and the number of donor hearts, so no alterations will be made to the Heart Allocation Zones at this stage. There was discussion about the sensitivity of the statistical test and how large the difference has to be for a significant difference to be detected. Manchester were particularly concerned about the size of their zone and the affect this has on their access to donor hearts.

**ACTION:** SR to investigate what magnitude of difference between registration and donors would result in a significant difference.  

5.2 **Heart Allocation Sub-Group**

5.2.1 **Sensitisation**

JyP hosted a telecon on 30/08/19 to discuss sensitisation and the group have agreed that sensitisation alone will not be used to prioritise patients. If an algorithm can be developed including other common variables that affect waiting time, it may be possible to incorporate that into the allocation system. SL has been liaising with Sharon Chih in Canada about their system.

**ACTION:** SL will liaise with SR about what data to include in this analysis of factors affecting waiting time to heart transplant and to see if this can be written into an algorithm. SL will report back to CTAG. LM to be involved in the Heart Allocation Sub-group during SR’s maternity leave.

5.2.2 **Super-Urgent Heart-Lung**

Following a declined request from Royal Papworth Hospital to the CTAG Hearts Adjudication Panel for Super-Urgent listing of a heart-lung patient, there was a request that CTAG reconsider the need for such a category. JyP wrote to the Heart Allocation Sub-Group and the Lung Allocation Sub-Group to request that they consider whether a Super-Urgent Heart/Lung category be introduced.

The Heart Allocation Sub-Group did not support the introduction of a Super-Urgent Heart-Lung category. The Lung Allocation Sub-Group will report back to CTAG in due course.

5.3 **CTAGH(19)35 – Summary of Adjudication Panel Appeals**

The report on adjudication panel appeals highlights that between 26/10/16 and 31/07/19 there were 60 applications for urgent adult heart registration, of which 48 (80%) were approved. This represents about 12% of all urgent heart registrations. There were 16 appeals for super-urgent adult heart registrations, of which 8 (50%) were approved, which represents about 7% of all super-urgent registrations. For children, 12 of 12 urgent paediatric registrations were approved. Regarding urgent
heart-lung appeals, 14 (63.6%) of 22 applications were approved, but there were also a number of super-urgent heart-lung appeals in the time period (all declined).

### 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 Heart-Liver Transplantation

Heart-Liver transplants are infrequent; QEH, Freeman and Royal Papworth have been involved in an informal group who review Lung-Liver transplant candidates.

The group discussed the frequency of Heart-Liver transplants (three Heart-Liver transplants in the past six years) and whether these transplants should only be carried out at certain centres. A prospective patient meeting listing criteria for both organs can be registered on the waiting list. If listing criteria are not met for either organ the relevant adjudication panel/appeals panel should be approached for permission. If the patient meets criteria for Urgent heart listing, registration can be done under UHAS, other patients will require Adjudication Panel approval if prioritisation is required.

It was agreed that co-location of CT and Liver teams was essential.

It was agreed that super-urgent listing should not be granted for heart-liver patients as the risk is likely to be excessive.

**ACTION:** JyP will also raise this at the CTAG Patient Group meeting.  

### 5.5 CTAGH(19)36, CTAGH(19)37 – Heart Transplantation Policy changes

POL229(/7) and POL228(/11) have had some minor alterations, the changes will be reviewed by TPRC prior to approval. Changes include the introduction of Super-Urgent listing criteria for paediatric heart transplantation and alterations to Urgent paediatric listing criteria as a result of this. The paediatric representatives need to decide which devices are classed as Super-Urgent and which are Urgent.

**ACTION:** MF and Zdenka Reinhardt will review wording and request any necessary alterations to Policy wording for paediatric patients.

The Super-Urgent paediatric category should be introduced in the new year, along with the ability to register a large paediatric on the urgent adult or super-urgent adult list to receive adult size hearts. The policy changes will go live at the point when these changes are made, which require IT changes.

There are also some changes to the lung policies that are underway which will mean a change in the offering process away from Group Offering. In order to not lengthen the offering process, centres will be asked to consider all super-urgent and urgent heart patients and heart-lung patients when an offer is made. There were some concerns about the allocation sequence being bypassed but members were reassured that the sequence will be honoured.

**ACTION:** CTAG need reassurance and JW/SR were asked to provide a report to CTAG following the introduction of any changes in offering on whether it is working correctly. SR/JW

Heart-Liver wording within the policy will need some alteration following discussions earlier today.

Another proposal to ensure offering times aren’t lengthened is to Group Offer the heart if three centres decline a heart based on poor function or history. SR mentioned that of the 600 DBD hearts offered during 2018/19, about 100 were declined three or more times based on poor function. This means that roughly 1 in 6 hearts would be Group Offered based on this trigger. Of these 100 hearts, only 1 was accepted and used, so given that there is a small chance of a transplant, this would speed up the process for those organs that are unlikely to be accepted. CTAG were in favour of this.

**ACTION:** JyP to take POL229 and POL228 to TPRC for approval after final edits based on discussion today. JyP

### 6 ODT Hub Update

#### 6.1 Organ offering changes and Fast Track triggers

JW has conducted a review within ODT Hub, identified issues all fall within 16 main themes. One overarching 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 more 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 their patients on the basis of function.

JMG commented that the Republic of Ireland has noted changes in the last couple of years, 6 ideal donor hearts have been offered by the Republic of Ireland but only two were used. JMG will work with JW to establish whether RoI hearts are Fast Tracked. JMG confirmed that there is an on-call retrieval team and will not wait for English NORS to arrive due to the increased delay this would cause. There is a minimum of an eight-hour delay between the initial offer and cross clamp so it should be achievable to get more RoI hearts into English hospitals. Royal Papworth and Manchester have both utilised RoI hearts in the past.

There have been no heart offers from England to RoI in the past year.

**ACTION:** JW and JMG will review further to maximise offering opportunities between the UK and the Republic of Ireland.

### 7 Statistics and Clinical Studies reports

#### 7.1 CTAGH(19)38 – Summary from Statistics and Clinical Studies

Since the last meeting Statistics and Clinical Studies have published the Annual Transplant Activity Report as well as the Organ Specific Annual Reports. The MCS report will follow shortly. Overall findings are that there are more donors but fewer transplants performed, particularly in cardiothoracic transplantation.

NHSBT and BTS are holding a Lung Summit to investigate and address the root cause for the reducing number of lung transplants in the UK and Statistics and Clinical Studies will be preparing a presentation for this meeting.

The Statistics and Clinical Studies team are working on the final stages of development of the Transplantation Infographics for centres, these should be available in the next few months. LM will be covering for SR from November when she goes on maternity leave.

Two publications are underway looking at the UK experience with HeartMate3 and HeartWare HVAD Left Ventricular Assist Devices produced by SS et al. and PREDICT-A, a model to predict PGD after Adult Heart Transplantation in the UK, developed by Sanjeet Singh (previous cardiothoracic fellow).

**ACTION:** Manuscripts to be circulated to the group once they have been published.

GH (NHSBT Cardiothoracic Clinical Research Fellow) will be continuing with the lung utilisation work that SR and John Dark have previously been involved with.

#### 7.2 CTAGH(19)39 – Summary of Heart-Lung Transplants

Since 1 April 2010, there have been 105 registrations for a heart-lung transplant of which 27 patients died on the list and 42 received a transplant. Of the 38 heart-lung transplants between 1 April 2010 and 31 March 2018, 31 patients (81.6%) survived to 90 days and 27 (70.7%) survived for the first year after transplant. Recent outcomes (following the introduction of Urgent Heart-Lung listing), have been worse with some centres reporting one year survival below 20%. The group agreed that these results need to improve significantly.

### 8 Reports and Discussion Points from the Chair

#### 8.1 CTAGH(19)40 – CT Centre Directors Telecon key discussion points

The minutes from the last meeting on 26th July 2019 were attached for information.

#### 8.1.1 CTAGH(19)41 – 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 hearts was 77.8% from retrieval surgeons and 68.5% from recipient surgeons. The national damage rate for retrieved hearts was 4% when reported by retrieval surgeons and 8% when reported by recipient surgeons, however it varied when the heart was retrieved by the same team as the recipient surgeon versus a different team; 2% versus 12%.

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 CTAGH(19)42 – Registry Form Returns
One of the ongoing issues CTAG has been trying to resolve is the Registry Form Return Rates. Some centres have a large number of these forms outstanding which means national outcome data is skewed. This has been discussed at CTCAG and the recent Centre Directors Telecon, 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 Annual Report. Most CTAG members support a financial penalty for centres that continue to show poor return rates and recommend that NHSE build this into contracts.

The VAD Database has similar issues with data completeness and inaccuracy of reporting. This will be discussed further at the MCS Meeting on 19th September.

**ACTION: SR to notify centres around April 2020 of their form return rates ahead of the publication of the next Annual Report on Cardiothoracic Transplantation.**

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 CTAGH(19)43 – RINTAG DCD Hearts Working Group Update
The DCD Working Group has now closed and DCD heart retrieval will be taken forward by the Implementation Board for the Joint Innovation Fund and RAG.

8.4 Joint Innovation Fund Bid (OCS)
PC thanked NHSBT and NHSE for their funding of DCD heart transplantation. The JIF bid was welcomed but certain modifications are required Karen Quinn (KQ) and DM will attend a meeting at Royal Papworth to go through these requirements. A working group with representation from all centres will be set up; PC will be in contact following the meeting.

8.5 CTAGH(19)44 – QUOD Update
The QUOD Biobank was established in 2012 and since then has supported 55 projects and currently holds over 80 BAL samples. Discussion took place within the group about whether centres would be happy to accept hearts for transplantation where an LV Biopsy had been taken – Queen Elizabeth Hospital, Royal Papworth and the Freeman Hospitals are all prepared to accept hearts which have had a biopsy sample taken; however Golden Jubilee, Harefield and Wythenshawe would not accept biopsied hearts due to a slightly increased risk of bleeding.

All centres are happy to take the biopsy sample for QUOD, and NORS teams will be fully trained in how to take this sample to avoid the need for cardiothoracic expertise when the cardiothoracic organs are not intended to be utilised.

There was also discussion about consenting recipients to receive organs that have had a biopsy taken. Further work is needed to explore the ethical and legal risks and ensure the biobank is future proofed.

9 Reports from sub-groups
9.1 CTAGH(19)45 – CTAG Clinical Audit Group (CAG) Chairs Report
The CTAG Clinical Audit Group Report to CTAG is attached. Comments to NAA

9.1.1 CTAGH(19)45a, CTAGH(19)45b, CTAGH(19)45c – Risk Adjustment and Predicted Risk in Heart Transplantation
SL raised risk adjustments and predicted risk in heart transplantation at the last CTCAG Meeting and the group agreed that the risk stratification model for heart transplantation should be looked at in more detail in light of alternative models published in the literature. Stephen Pettit (SP) produced a detailed response, looked at other models and submitted his suggestions to CTCAG.

One of the challenges currently delaying this piece of work is the lack of returned forms, this information is vital in determining the different variables affecting outcome and is another reason for
the timely completion and return of registry forms to NHSBT. SR will work with SL and SP to review the NHSBT model alongside the literature and data available and report back to CTCAG.

9.1.4 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 welcomed to stand for re-election. Requests for expressions of interest in the role of MCS representative will be circulated in October 2019.

9.2 CTAGH(19)46 – 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.

10 Heart Utilisation
10.1 Heart Utilisation Sub-Group
The Heart Utilisation Sub-Group led by Aaron Ranasinghe have held 2 telecons since the last CTAGH meeting and are working on defining the Ideal Heart Donor. Once this work has been completed the group will look at the individual ‘ideal donor organs’ which are declined and review the reasons for the decline before making recommendations to help increase the rate of heart utilisation. There were comments about a DBD donor being converted to DCDs and whether this was a trend. Centres were reassured that this would only happen if the family requested it in order to allow donation to happen, and that this is closely monitored.

10.2 CTAGH(19)47 – Centre Specific Activity Report (first five months)
The Centre Specific Activity Report identified that 61 hearts were used for transplant in the first five months of this year, 66 hearts were used for transplant in the same time period last year, which is an 11% drop on top of an 8% drop last year. The total number of hearts transplanted this year compared to last year includes DCD and DBD hearts, the figure would be 9% lower again if DCD Hearts were not included.

11 For Information
11.1 CTAGH(19)48 – Transplant Activity Report
For information only, no comments raised.

11.2 CTAGH(19)49 – NHSBT ICT Update for Advisory Groups
For information only, no comments raised.

12 Any other business
ASi will contact centres about Cytosorb proposal.

PC thanked ASi for allowing Papworth to go ahead with the first DCD heart-lung transplant. The patient is home and well at 90 days post-transplant. The organs were put onto the OCS for 8 hours prior to transplant and functioned well.

Date of next meetings
CTAGL Lungs – Thursday 26th September 2019 – 1100-1600 @ Venue TBC
CTAG Patient Group – Wednesday 13th November 2019 – 1230-1600
Coram, 41 Brunswick Square, London, WC1N 1AZ (Sandwich Lunch 1200-1230)