

**NHS BLOOD AND TRANSPLANT
ORGAN DONATION AND TRANSPLANTATION DIRECTORATE
THE NINETEENTH MEETING OF THE NHSBT CTAG HEARTS ADVISORY GROUP
ON WEDNESDAY 18 MAY 2022
VIA MICROSOFT TEAMS**

MINUTES

Attendees:

Rajamiyer Venkateswaren	CTAG Hearts Chair , Centre Director, Wythenshawe Hospital
Ayesha Ali	NHS England
Marius Berman	Associate Clinical Lead Organ Retrieval, NHSBT
Robert Burns	Co-Chair CTAG Patient Group
Paul Callan	Consultant Cardiologist, Manchester University NHS Foundation Trust
Colin Chue	Consultant Cardiologist, University Hospitals Birmingham
Ian Currie	Associate Medical Director – Retrieval, NHSBT
Philip Curry	Consultant Cardiac / Transplant Surgeon. Golden Jubilee National Hospital
Jonathan Dalzell	Centre Director, Cardiologist, Golden Jubilee National Hospital
John Forsythe	Organ Utilisation Programme, NHSBT
Diana Garcia Saez	Specialty Doctor Cardiothoracic Surgery and Transplantation, Harefield
Dale Gardiner	Associate Medical Director – Deceased Organ Donation, NHSBT
Margaret Harrison	CTAG Lay Member Representative
Katrijn Jansen	Consultant Cardiologist, Freeman Hospital, Newcastle
Delordson Kallan	CTAG BHSI Representative
Sern Lim	Cardiologist, Queen Elizabeth Hospital, Birmingham
Guy MacGowan	Cardiologist, Freeman Hospital, Newcastle
Derek Manas	Medical Director, OTDT, NHSBT
Emiliano Mazzaretto	Team Manager, London Organ Donation Services Team
Simon Messer	Senior Cardiothoracic Surgical Registrar, Royal Papworth Hospital
Jasvir Parmar	Chair CTAG Lungs, Royal Papworth Hospital
Stephen Pettit	Centre Director, Cardiologist, Royal Papworth Hospital
Zdenka Reinhardt	Cardiologist, Freeman Hospital, Newcastle
Fernando Riesgo Gil	Consultant Cardiologist, Royal Brompton and Harefield Hospital
Sally Rushton	Principal Statistician, Statistics and Clinical Research, NHSBT
Steven Shaw	Cardiology, Wythenshawe Hospital
Jacob Simmonds	Consultant Cardiologist, Great Ormond Street Hospital
Laura Stamp	Lead Nurse Recipient Coordinator, NHSBT
Sarah Watson	NHS England
Craig Wheelans	National Services Division, NHS Scotland
Julie Whitney	Head of Service Delivery, OTDT Hub, NHSBT
Luke Williams	Cardiology, Royal Papworth Hospital

In attendance:

Nkechi Onwuka	Statistician, Statistics and Clinical Research, NHSBT
Caroline Robinson (Minutes)	Clinical and Support Services, NHSBT
Lewis Simmonds	Statistician, Statistics and Clinical Research, NHSBT

Apologies received:

Lynne Ayton, Richard Baker, Anthony Clarkson, Catherine Coyle, John Dunning, Anushka Govias-Smith, Anna-Maria Macleod, Tracey Rees

No.	Item	Action
	Welcome and Apologies	
	R Venkateswaran welcomed everyone to the meeting and details of apologies were given (see above).	
1.	Declarations of Interest in relation to the Agenda CTAGH(20)22	
	There were no declarations of interest in relation to today's Agenda.	
	<i>Please note that it is the policy of NHSBT to publish all papers on the website unless the papers include patient identifiable information,</i>	

	<i>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</i>	
2.	Minutes and Action Points of the CTAGH Meeting held on 06 October 2021 CTAGH(M)(21)02 and CTAGH(AP)(21)02	
2.1	The Minutes of the CTAG Hearts Meeting held on 6 October 2021 were accepted.	
2.2	The following Action Points were discussed:	
2.2.1	<u>AP1: Non-compliance with Heart Allocation</u> - It was previously agreed to form a fixed term working group to discuss issues relating to urgent Heart-Lung listings. It has subsequently been agreed that all these listings will go through the adjudication panel process. An IT project has been completed to formalise listings so that the NTXD system can deal with the combined urgency for these patients. This went live on 11 th May 2022. New policies and registration forms are also in place to cover these arrangements. No working group is therefore required.	COMPLETE
2.2.2	<u>AP2: Long waiting patients on urgent list</u> - D Kallan reported that several meetings have taken place regarding long waiting patients on the urgent list and a writing committee has been put together to review CTAG guidelines. A rough draft has been completed and it is hoped to circulate the guidelines in June. A data group will also look at the demographics of these patients and past transplants and will include patients on the waiting list as well.	Review at Autumn CTAG Hearts meeting
2.2.3	<u>AP3: LVAD Complications Project</u> : This project, proposed by S Lim and endorsed by CTAG in 2020, aims to review outcomes of urgent heart transplantation in patients with LVAD-related complications in the UK and to identify patients at high risk of mortality from transplantation. The proforma for urgent appeals has been re-circulated.	COMPLETE <i>See Item 8.4</i>
2.2.4	<u>AP4: LVAD Complications Project</u> : CTAG members felt that more granular, serial data was needed before this project could be published in the public domain but that the aim should be to share the data in future. More data are presented under Item 8.4.	<i>See Item 8.4</i>
2.2.5	<u>AP5: COVID-19 Update</u> : L Mumford's presentation from the autumn meeting was circulated on 1 November 2021	COMPLETE
2.2.6	<u>AP6: COVID-19 Update</u> U Stock agreed previously to investigate why Harefield data is not populated in the data shown for hospital bed occupancy data. R Venkateswaran will discuss this off-line with J Dunning.	R Venkateswaran / J Dunning
2.2.7	<u>AP7: Use of Sherpak</u> : A paper was circulated previously showing data from 22 transplants that used Sherpak rather than traditional ice boxes to transport an organ.	COMPLETE <i>See Item 10.2</i>
2.2.8	<u>AP8: Donor Swan-Ganz catheter for cardiac transplantation</u> : A letter from Professor Jim Egan, Director of Organ Transplant Ireland (ODTI) points out that Swan-Ganz catheterisation is not part of ODTI retrieval processes. CTAG members were asked to consider that a retrieval without echo or Swan-Ganz could incur travel cost implications if the organ is accepted without clear indications of its potential utilisation.	<i>See Item 10.7</i>
2.2.9	<u>AP9: CTAG Audit Group</u> : The group has now been disbanded and members informed. A new CTAG Research and Innovation Group is now set up and has held its first meeting.	COMPLETE <i>See Item 11.3</i>
3.	Medical Director's Report	
3.1	<u>Developments in NHSBT</u>	
	D Manas highlighted the following: <ul style="list-style-type: none"> The outcome of the Spending Review is expected imminently from the Department of Health. It is hoped that there will be funding for NRP and DCD Hearts. ANRP has shown great results. TA-NRP is currently on hold because of concerns regarding brain perfusion. A trial is being set up to look into this and it is hoped that issues can be resolved to enable the UK to align with the rest of the world. The Organ Utilisation Group, chaired by Steve Powis (NHS England) will publish its recommendations shortly following ministerial approval. A working group will be set up to implement the recommendations. 	

	<ul style="list-style-type: none"> • ODT has now joined with the Tissue and Eyes Service (TES) to form OTDT. A separate working group to look at issues around use of heart valves may be set up under the auspices of CTAG. • Histopathology – A plan is in place with NHS England to develop this service with an interim plan in place over the next 15 months while this is finalised. <i>See Item 12.3</i> • Photography – A document has been circulated explaining rules around imaging. No images should be taken on personal mobiles and it is recommended that SNODs are responsible for any photography of organs during retrievals. • There are no incidents of non-compliance and no CUSUM signals to report. • A humanitarian waiver has been granted by the MHRA to use the mOrgan device to support retrieval and transplantation of a heart for a named patient at Great Ormond Street Hospital. • Advisory groups are being encouraged to hold at least one face to face meeting per year to support and facilitate networking across centres. The next CTAG Hearts meeting in the autumn will be face to face and further information will follow. 	
3.2	<u>New Appointments</u>	
	<p>The following new appointments have been made to a Board of 7 Associate Medical Directors:</p> <ul style="list-style-type: none"> • Richard Baker becomes AMD for Clinical Governance with Sanjay Sinha taking on the role of surgical Clinical Governance lead. • Lorna Marson becomes AMD for Research & Development with oversight of BTRU and QUOD and the UK Organ Donation network. • Ian Currie has been appointed as a new AMD for Retrieval from 1 April. <p>Each Associate Medical Director will take responsibility for an advisory group and for CTAG this will be Dale Gardiner.</p> <ul style="list-style-type: none"> • The Organ Utilisation Programme (OUP) continues with interim funding until the end of June and will include ARCs, CLUs, digital infrastructure and education. Workstream leads for OUP appointed to support Claire Williment's work are Agimol Pradeep, Jessica Jones and Helen McManus. Although the outcome of the funding review is not yet known, OUP work remains an important programme that includes ARCs, CLUs and education and interim funding continues for 3 months from April. Diana Garcia Saez also retains the Organ Utilisation lead role. • A lay members' appointment committee meets next week to recruit members. M Harrison is retained for CTAG working alongside S Ghosh. 	
4.	<u>Governance Issues</u>	
4.1	<u>Non-Compliance with Heart Allocation</u>	
	There were no issues of non-compliance reported.	
4.2	<u>Clinical Governance Report - CTAGH(22)32</u>	
	<p>This paper was circulated for information and D Manas gave an update in R Baker's absence. From a retrieval point of view there have been no recent incidents.</p> <ul style="list-style-type: none"> • A short vessels issue was highlighted. It is not uncommon to need to put in a graft following short vessels retrieval but the number of times this happens is unknown. It was agreed that if the retrieval team has followed the protocol, a short vessels outcome would not be an incident. However, if this were to happen recurrently, it is likely an SAR would result. • <u>Photography and filming</u> – centres are reminded not to film any part of the retrieval, heart function, echos on personal mobiles. Any photography needs to be done through the official route, ie a SNOD iPad or trust device. When EOS is replaced, imaging will be included on the new system. 	
4.3	<u>CUSUM Monitoring of 30-day outcomes following heart transplantation - CTAGH(22)01</u>	

	This paper monitoring short term mortality following heart transplant was circulated prior to the meeting. In April 2022 the outcome for heart transplant CUSUMs was changed from 30 days to 90 days mortality following agreement from CTAG. DCD heart transplants are also now included in the expected mortality rates as well as the monitoring cohort. Over the 6 months since the last CTAG meeting there have been no signals in heart transplantation CUSUM reporting.	
4.3.1	<u>Heart CUSUM changes – CTAGH(22)02</u>	
	This paper was circulated prior to the meeting and shows how the applied changes from 30 to 90 days mortality impact on the baseline mortality rates. The baseline is taken from Jan 2015 to Dec 2018 and shows the 8.7% mortality rate for adults has extended to 13.8% for 90 days and then reduces to 13.3% when DCD transplants are included. For paediatric patients the rate remains at 3.5% (ie, no impact). Centres with lower than average mortality rate will receive two CUSUM charts, one comparing against the national rate and one against their own expected rate. Only those signals in the national rate chart are considered formal signals. If the rule of 90 days was in place in 2020-21, Harefield would have had one signal rather than two signals. The reason why the base period was 2015-18 was queried and it was noted that this is to ensure there is no overlap with the current monitoring period.	
4.4	<u>Group 2 Transplants</u>	
	There were no recent transplants to discuss.	
5.	OTDT Hub Update	
5.1	<u>HTA B form returns – CTAGH(22)03</u>	
	This paper was circulated. Centres were thanked for improving return rates and clearing the back log of returns.	
5.2	<u>Performance Report for Registry Returns – CTAGH(22)33</u>	
	This paper is a prototype performance dashboard for all organ groups (with combined heart and lungs) where there is interaction with NHSBT Hub showing offer time compliance, HTA B returns compliance and return of transplant, 3 month and annual follow up record forms. This will be sent to units from this month onwards and should inform centres of their compliance and what forms remains outstanding. Data will be collated shortly for the annual report, so centres were reminded to return all information and forms needed as soon as possible.	
5.3	<u>Super Urgent Liver – 3 months report – March 2022 – CTAGH(22)04</u>	
	This paper was circulated prior to the meeting. When a liver has been accepted for a super-urgent patient, if CT organs are under offer, CT offering will switch to group offering if not already at that stage to save time. The pathway was introduced in April 2021 under an opt in trial where liver centres could choose to activate the pathway when accepting a liver for a super-urgent patient. In November 2021, a pilot began where this pathway would be implemented for all super-urgent liver acceptances where CT offering occurs. J Whitney, I Currie and M Berman are meeting on alternate weeks to review each case when the pathway is utilised to identify trends and to recommend changes going forward. It was agreed that time can be saved by CT centres focussing on details of an offer at an early stage.	
6.	DCD Hearts	
6.1	<u>JIF Board meeting update</u>	
	S Watson stated that the DCD Heart meeting was held last week. While the quality and support for the DCD programme makes it a high priority, further funding is still not clarified and therefore has only been extended for 3 months currently. A letter from all units and the Chair of the Patient Group to the JIF Board has been drafted indicating national support for the DCD Hearts programme. M Berman also stated that he had presented the outcomes of 50 DCD heart transplants at the International Society for Heart and Lung Transplantation (ISHLT) Conference which highlighted the UK as the only country in the world to have a national collaborative programme for DCD. ACTION: Centre Directors to send their electronic signatures to C Robinson to be included on the letter to the JIF Board	Centre Directors
6.2	<u>DCD hearts regular report – CTAGH(22)05</u>	

	<p>This quarterly report covers the period from 1 February 2015 to 28 February 2022 and presents DCD retrieval attendance, utilisation of other organs, post-transplant survival and support, and DCD heart offering. Since the start of JIF DCD heart pilot and the end of February this year there were 50 transplants. Overall, 206 hearts have been retrieved and 175 transplanted. The 1-year survival rate is very similar to DBD (DCD 85.7%; DBD 83.7%). A total of 29 patients died post DCD transplant and 62 patients required mechanical support post-transplant within 30 days (36%). This is slightly higher than DBD. Full information is detailed within the report.</p> <p>M Berman also highlighted issues around TA-NRP from the recent ISHLT. While the UK has largely stopped TA-NRP, Europe/US presented multiple TA-NRP programmes producing good results mainly due to reduced ischaemic time. Three hospitals are working with TA-NRP currently, but it needs national support to move forward, and this could help with funding issues.</p> <p>It was agreed that following confirmation of full funding of DCD and agreement by the JIF Board, a move should be made to adopt the DBD offering sequence for DCD, acknowledging that it will take time to implement at the Hub. In the interim, if a DCD becomes a DBD it has been agreed that:</p> <ul style="list-style-type: none"> • <i>If offering is underway but not accepted OR heart has been placed but the NORS team are not en route a DBD matching run will be generated and named patient offering commenced.</i> • <i>If NORS team en route, keep with allocation.</i> <p>ACTION: J Whitney to operationalise offering when DCD becomes a DBD</p>	
7.	Heart Utilisation	
7.1	<u>CLU Update –</u>	
	In A Ranasinghe's absence, D Garcia Saez gave the CLU update. The 2 nd phase of the Clinical Lead for Utilisation (CLU) programme is now complete, and confirmation of further funding is still awaited. Interim funding until the end of June to continue the programme has been agreed. Three well attended meetings have been held, chaired by A Ranasinghe, where many local and national projects have been discussed and these will be included in the National Utilisation Conference to be held on 27 May. All centre directors should have received invitations to this.	
7.2	<u>Offer Review Schemes – heart – CTAGH(22)35</u>	
	<p>This paper defines a group of “higher quality” donors (HQD) that should have a high utilisation rate. An abdominal utilisation scheme was led by Chris Callaghan pre pandemic and has now re-started. The offer review scheme for Lungs was discussed at the CTAG Lungs meeting in April and has now gone live. The principle is to ensure that any donor organ meeting the criteria for a higher quality donor will be utilised. All offers will be reviewed by A Ranasinghe, and any organs turned down that appear to meet the criteria will be discussed with the relevant centre director. Declines for logistics reasons will also be scrutinised and NHS England would like to be informed of particular issues at centres which prevent them from accepting offers. IVS less than or equal to 12 mm in the criteria was queried as 13 mm is now recommended as the threshold. It was confirmed that this will be changed within the criteria. All criteria will be reviewed and modified as necessary.</p> <p>ACTION: D Garcia Saez to alter IVS from less than or equal to 12 mm to less than or equal to 13 mm in HQD definition</p>	
7.3	<u>Donor heart utilisation – national figures – CTAGH(22)06</u>	
	A report was presented which tracks utilisation rates over time for offered hearts and lungs, by DBD/DCD and HQD status. This will be a regular report at future meetings to monitor any impact from the OU initiative. Those attending were asked for ideas to make the data shown more accessible.	
7.4	<u>Organ Utilisation Programme Update –</u> <i>See Item 3.2</i>	
7.5	<u>Organ Utilisation Group Update</u>	
	J Forsythe gave an update on the work of the Organ Utilisation Group which has been chaired by Steve Powis (NHS England). The report of the group is close to	

	<p>completion and a ministerial steer is now awaited. The Secretariat and those who have contributed were thanked. A patient survey has also produced 300 responses. One theme highlighted by patients that does not currently function well was the gap between referral and transplant and transfer from one transplant unit to another unit.</p> <p>Around 12 recommendations will come out of the work of the OUG and these form 6 different themes. Two areas to consider particularly are (i) keeping the patient at the heart of the service to ensure patient and patient group views are noted and (ii) operational infrastructure at the level of the trust, unit and commissioning.</p> <p>For CT transplantation, 2 issues are highlighted:</p> <ul style="list-style-type: none"> • <u>Workforce</u> – the fragility of the service and loss of staff over the last 5 years show, highlighting that CT transplant surgery is a global market. Transplant surgery is something that feels like it is done in spare time and not as the primary role. • <u>Data</u> – while data for transplant surgery is very good compared with elsewhere, the availability of real time data could be better. Discussions with NHS Digital show that designing something specifically for donation and transplant would be expensive. It is essential that whatever is developed overall in future should be done at the highest level and good for donation and transplant as well. 	
7.6	<u>ARC update</u>	
	M Berman stated that there is no progress on this project for Heart or Lungs currently.	
8.	Heart Allocation	
8.1	<u>Heart Allocation Sub-group (04.04.22) – CTAGH(22)07 and CTAGH(22)31</u>	
	<p>S Lim (Chair of Heart Allocation sub-group) stated that this group has been formed due to an increased numbers of urgent patients and longer waiting list times. Typically, waiting time is now 2 months. The revision of the heart allocation scheme is being considered as it is felt the proposed 6 tier system is unworkable. It was previously agreed to examine <i>Category 21 - inotrope use</i> to understand the kind of patients being listed as this is the largest group on the urgent list. Thanks to all centres for their co-operation and providing data. The measurable criteria for urgent listing are defined into 5 categories:</p> <ul style="list-style-type: none"> • Symptomatic deterioration • Recurrent admissions • High PVR • Cardio renal/hepatic • Shock <p>Data from 120 patients at all centres is being analysed to develop criteria for listing for inotrope use, eg bilirubin, creatinine, GFR or TPG level or PVR level. Another meeting of the group will be held in the next few months and there will be an update at the next CTAG Hearts meeting.</p>	
8.2	<u>Heart Liver update</u>	
	<p>S Lim stated that combined heart liver transplants will be part of the discussions of the Heart Allocation Group. Some work has been done on this topic in the US which may be useful. In last 10 years, there has been less than 1 heart liver transplant per year. However, this year the number of patients waiting has increased and there are now 6 patients on the list for transplant (4 at Newcastle; 2 at Birmingham), half of whom are on the urgent heart waiting list. However, it is noted that combined transplants do carry higher risk so adding these to an urgent list that is already very high when limited organs are available remains a difficult area to investigate in the Heart Allocation Group. One complication is ineligibility for mechanical support or need for inotropes. It was noted that while numbers are small, transparency and equity for patients is essential and there is a responsibility to use a limited number of organs wisely. Outcomes should become part of a regular report coming to CTAG Hearts. It was also agreed that a complex recipient meeting discussion would be important.</p> <p>ACTION: Heart liver results will be reported in the Annual Cardiothoracic Report</p>	S Rushton

8.3	<u>Summary of Adjudication Panel Appeals – CTAGH(22)08</u>	
	<p>The paper circulated summarises patients referred for urgent or super-urgent listing between October 2016 to end February 2022.</p> <ul style="list-style-type: none"> Urgent Heart Appeals - Adults - 119 appeals (average of 2 per month) – 98 approved (82.4%). Super Urgent Heart Appeals – Adults - 19 appeals – 9 approved (47.4%). Most patients qualify for super urgent listing due to being on short term mechanical support. Urgent Paediatric Appeals – 31 appeals – 30 approved (96.8%). Urgent heart lung appeals – These are approved by the Lung Adjudication Panel as there is a priority for lung approval or patients are listed as urgent lung recipients. Appeals go to the Heart panel if they do not meet urgent heart criteria – 28 appeals – 20 approved. <p>The issue of whether specific indications/complications that go to appeal and are always approved should need to go through the adjudication process. It was agreed that it is important to learn from the adjudication discussions and so there will be no change at present.</p> <p>ACTION: Future reports will cover a more recent period of the last 3 years.</p>	S Rushton
8.4	<u>LVAD complications project – CTAGH(22)34</u>	
	<p>This project was proposed by S Lim and J Parameshwar to review the outcomes of patients who are accepted for urgent transplantations when they have LVAD complications. An analysis of 66 patients urgently listed due to LVAD-related complications was presented at the last CTAG Hearts meeting. Forty-eight patients received a heart transplant, and the 1-year survival rate was 56%, significantly lower than for other urgent heart transplant recipients (88%). The cohort shown in the circulated report for this meeting is now 61 patients and while this remains a small sample size this does include at least 1 patient per adult transplant centre. Survival is 65.2% up to 90 days so there is still a poor outcome for these patients. Information on the types of variables influencing outcomes is also summarised in the paper eg systemic infection, type of LVAD and VAD duration, BMI, ischaemic time, centre. It was agreed that this is valuable work and further discussion is needed to identify specific factors that cause poor outcomes to guide future decision making. It was also noted that all centres are now using the same device.</p>	
8.5	<u>Zonal allocation review – CTAGH(22)10</u>	
	<p>This report shows that no alteration of the heart allocation zones is needed currently. Additional tables in the report detail organ utilisation (26%) across the zones and the proportion of transplants performed for non-zonal donors (63%) rather than from zones (37%).</p>	
8.6	<u>Selection and Allocation policy updates – CTAGH(22)11 and CTAGH(22)12</u>	
	<p>These policies are circulated for information and are now live on the ODT website.</p>	
9.	Statistics and Clinical Research reports	
9.1	<u>Summary from Statistics and Clinical Research – CTAGH(22)13</u>	
	<p>This paper was circulated for information. The annual report will be produced shortly.</p>	
9.2	<u>Latest Centre activity summary – CTAGH(22)14</u>	
	<p>D Gardiner presented this paper which shares data of heart transplants at each CT centre and includes details from Canada. Despite Canada having 58% of the UK population, as many heart transplants are done there as in this country. This data is available to any centre to use as a powerpoint presentation.</p> <p>ACTION: All to give feedback/ideas to D Gardiner / S Rushton and to request a powerpoint presentation if required.</p>	
10.	Reports and Discussion Points from the Chair	
10.1	<u>RAG Update (29/03/22)</u>	
	<p>M Berman stated that DCD, multi-visceral/CT issues discussed in <i>Item 10.1.1</i> and abdominal NRP were all discussed at RAG.</p>	
10.1.1	<u>Laparotomy needed for donors of CT and Multi-visceral (MV) organs</u>	

	<p>About 20 donors per year donate MV organs. As part of the donor operation, the viscera need to be assessed by the abdominal team. In many cases, the CT team insists that CT assessment goes first. In both cases, irreversible surgery will start for MV and CT recipients on the instruction of the donor surgeons and there may be a delay in cross clamp to allow recipient surgery to reach a certain stage. Cross clamp delay for MV recipients can be longer than CT cross clamp delay. It is therefore reasonable for the MV assessment to go first to avoid delay in the CT recipient centre and in the donor operation while the MV recipient reaches a stage for cross clamp to proceed. This has been discussed in the CT Centre Directors' meeting and it is agreed that in the interests of a smooth process with the minimum cross clamp delay and delays in CT recipient surgery, the MV assessment will now take place first.</p> <p>ACTION: I Currie/M Berman to prepare a paragraph on this for the NORS guidelines</p>	I Currie / M Berman
10.1.2	<u>XVIVO Study (papers available)</u> – CTAGH(22)15 , CTAGH(22)16 and CTAGH(22)17	
	M Berman stated that NIHP approached 3 centres (Newcastle, Papworth and Birmingham) to join an international, multi-centre trial to evaluate non-ischaeamic heart preservation utilising XVIVO Heart Solution with non-ischemic hypothermic perfusion of the donor heart with the XVIVO Heart Perfusion System. This trial has been designed to compare this novel method of preservation with cold static perfusion and aims to randomise 202 patients from 8 transplant centres in 7 European countries. 40 patients will be recruited in the UK. Further pre-clinical studies, utilising the XVIVO NIHP System have demonstrated safe preservation in porcine models for periods of 24 hours. It is an MHRA approved device, and the 3 teams have received their training in the past 4-6 weeks. There is a specific consent form for recipients. Work is ongoing with the Hub to ensure there is no disruption to NORS activities. Further information is in the documents circulated.	
10.2	<u>Use of Sherpapak</u> – CTAGH(22)18 and CTAGH(22)19	
	<p>The ISHLT abstract on the use of Sherpapak for Organ Transportation in the UK was circulated detailing results for 30 patients. A further 800 patients are on the Guardian Registry. Despite results indicating better outcomes when Sherpapak is used compared with an ice box, reduced primary graft dysfunction and reduced intensive care stays, R Venkateswaran stated that without all centres co-operating in use of Sherpapak, it is not possible to move forward with this currently. There is no funding and a large number of other projects and trials ongoing. It was suggested that co-funding and sharing responsibility for outcomes is something that can be discussed with Sherpapak.</p> <p>ACTION: R Venkateswaran to discuss possible next steps with Sherpapak to see what further support is possible</p>	R Venkateswaran
10.3	<u>Custodial v. St Thomas trial</u>	
	<i>See Item 10.6 below</i>	
10.4	<u>Signet Trial</u> - CTAGH(22)20	
	<p>J Dark attended the meeting to highlight the Signet Trial. This study funded by NIHR was originally presented to CTAG in Autumn 2020 and will randomise a total of 2600 DBD donors to receive either simvastatin or standard care. Follow up is done by the transplant registry. If CTAG members are involved in another study or service evaluation affecting early outcomes of cardiac transplant patients, they are asked to inform the Signet trial. Donor centres are unblinded so they know what drug to give, but recipient teams and recipient centres are blinded so other studies will not be aware of which of their donors have received simvastatin or have received standard care. In most studies there will be an equal number of statin and non-statin donors in each arm of a study. An independent statistician can confirm this when details of the donor numbers in a study are sent through to Signet.</p> <p>ACTION: All those involved in other studies to contact J Dark to negotiate a co-enrolment process.</p>	All those involved in research studies
10.5.1	<u>QUOD Update</u> – CTAGH(22)21	
	<ul style="list-style-type: none"> • QUOD has now restarted and continues to take BAL samples and biopsies from non-transplantable hearts. • M Berman gave an update on another project to take biopsies from transplantable hearts (from donor and recipient). Some concern has been 	

	noted regarding bleeding from the biopsy site, so a protocol is being developed in collaboration with Cambridge University and this is now being finalised with QUOD and V Gauden (NHSBT). Consent will be needed at both donor and recipient sites.	
10.5.2	<u>QUOD named UK Biobank of the Year (paper available) – CTAGH(22)22</u>	
	Information about this award was circulated prior to the meeting prior to the meeting.	
10.6	<u>F-CUSTOSS – CTAGH(22)23, CTAGH(22)24 and CTAGH(22)25</u>	
	L Williams from Papworth presented details of the <i>Feasibility study for Randomised Controlled Trial of C_Ustodiol-HTK vs S_t Thomas' solution for cardioplegia and cold S_tatic Storage of UK donor hearts in cardiac transplantation (F-CUSTOSS)</i> . This is a randomized control trial to compare the 2 preservative solutions approved for use in the UK. Currently there is little evidence on which solution is better. Before a large trial and application for funding is considered, the feasibility will be investigated by looking at the results from 50 hearts (25 using one solution and 25 using the other). The trial will also collect data around those who receive the correct intervention, data completion, primary graft dysfunction, 30-day mortality, length of stay and post-operative complications. Custodial will be provided free to all centres who will be unaware of which solution is to be used. The study will be sponsored by Papworth R&D with some input from NHSBT Statistics and there is budgeting for research nurses in each of the 6 centres. SNODs will be responsible for getting consent and randomization will be done centrally and NORS teams will need to take both solutions with them, only finding out which solution is to be used when they reach the donor centre. Data analysis will be done mainly at Papworth. Training will be given on storing the heart in the solution. ACTION: L Williams will have a separate meeting about the study with NORS teams	L Williams
10.7	<u>Workplan update</u>	
	The CTAG Hearts Workplan for 2021-24 was circulated at the last CTAG Hearts meeting. Priorities already established continue to be: <ul style="list-style-type: none"> To allocate heart to urgent patients on the waiting list according to need but also achieving good outcomes and work has begun to develop a new urgent heart allocation scheme. To increase the number of hearts for transplantation and the chances of listed patients receiving a transplant by agreeing a donor optimisation process and fully funded DCD heart retrieval service. ACTION: R Venkateswaran will contact I Currie/M Berman regarding donor management to increase heart utilisation and transplantation.	R Venkateswaran
10.8	<u>Donor heart acceptance from Irish donors</u>	
	This issue where hearts not utilised in the Republic of Ireland are offered to UK recipients was discussed in the previous CTAG Hearts meeting. Retrieval will be done by the Irish team, but there will be no Swan Ganz as only direct pressure measurement and visual inspection are required by the Irish service. No offers would be made without transthoracic echo. A UK team would need to fly to Ireland to bring back the heart to a recipient centre which has cost implications. However, it was acknowledged that Irish data is very good and those at the meeting agreed that providing the donors are young with a normal echo, have good blood pressure recorded and no use of inotropes, it would be good to hear about any offers. From the patient perspective, although this carries some increased risk, declining an offer would also carry a risk for a recipient who is already very sick. Journey times are a factor due to ischaemia, so possible use of Sherpapak rather than a normal ice box will be investigated. ACTION: 1) D Garcia Saez will feedback to J Dunning who was absent from the meeting 2) Venkat will respond with the meeting's feedback to Jim Egan, Organ and Donation Transplant Ireland.	D Garcia Saez / R Venkateswaran
10.9	<u>Heart Tool live on the ODT Clinical Website here (and directly here)</u>	
	This risk communication tool is now live and all centres are encouraged to use it in consultations with their patients.	

11.	Reports from sub-groups	
11.1	<u>CTAG Patient Group (12/05/21), new co-Chair and future meetings (22/06/22 and 07/12/22) – CTAGH(22)26 and CTAGH(22)27</u>	
	R Burns, the new Co-Chair of the Patient Group was welcomed to the group and details of his background and a regular report he will provide to this meeting were circulated. He highlighted key themes of continuity of care and communication as mentioned in <i>Item 7.5</i> above. The Patient Group will be aligned to the key issues being raised and it is hoped there will be wider patient and charity engagement in the meetings. The next meeting of the Patient Group will be on 22 June. R Burns was thanked for his active engagement in this meeting and in CTAG Lungs.	
11.2	<u>CT Centre Directors' meeting (01/04/22 and 13/05/22)</u>	
	In addition to topics mentioned elsewhere in these Minutes, J Parmar highlighted the following issue discussed at the Centre Directors' meetings: <ul style="list-style-type: none"> • <u>EVUSHELD</u> – this has been authorised for COVID-19 prevention by the MHRA after meeting the UK regulatory standards of safety, quality and effectiveness but is yet to be approved by NICE. The treatment aims to provide those with little or no response to vaccines with long lasting antibodies. • <u>National CT meeting (replacing the CQUIN meeting)</u> – 16 June - details and invitations to this virtual meeting have been sent to all centre directors to cascade to their teams. The agenda will be circulated shortly from NHS England. 	
11.3	<u>Start of CTAG Research and Innovation Group (11/5/22)</u>	
	The first meeting of this group took place on 11 May replacing the CTAG Audit group which had been largely inactive for 2 years. The new R&I group aims to focus clinicians on research that can be developed across all the centres. <ul style="list-style-type: none"> • An example highlighted is a bio resource application for recipients which is going into the MRC which will provide an infrastructure to deliver high level research post-transplant for recipients. • QUOD was unable to function well in pandemic and there have been low levels of samples in the bank so it is hoped this will now improve. Another meeting will be held in 3-4 months' time to discuss where to focus attention. Some themes to be developed include PGD, quality of life and post-transplant outcomes. It was acknowledged that without more funding it will not be possible to do sustainable audit in order produce high quality research.	
12.	For Information	
12.1	<u>Transplant Activity Report</u>	
	Go to the following page for information: https://www.odt.nhs.uk/statistics-and-reports/annual-activity-report/	
12.2	<u>NHSBT ICT Update for Advisory Groups – CTAGH(22)28</u>	
	This paper was circulated for information.	
12.3	<u>Histopathology Update – CTAGH(22)29 and CTAGH(22)30</u>	
	An update on the service being developed was circulated for information.	
13.	Any other business	
13.1	<u>Date of next meeting</u>	
	The next meeting is scheduled for 9 October 2022. This will be a face-to-face meeting and further information will be circulated in due course. There will not be a virtual option for the meeting, so members are encouraged to attend or send a representative.	

Dates of other CTAG meetings

CTAG Patients Group – Weds 22 June 2022 - 10:30-13:30 via Microsoft Teams

CTAG Lungs Meeting – Weds 28 September – 10:30-15:00 – via Microsoft Teams

CTAG Hearts Meeting – Weds 9 November 2022 – 10:30-15:00 – Face to Face TBA

CTAG Patients Group – Weds 7 December 2022 – 10:30-13:30 – via Microsoft Teams