

**NHS BLOOD AND TRANSPLANT
ORGAN DONATION AND TRANSPLANTATION DIRECTORATE
CTAG HEART ALLOCATION SUB GROUP (HASG)
FACE TO FACE MEETING
THURSDAY 5TH APRIL 2018 10:00 – 16:00**

**MARYLEBONE ROOM, PARK CONFERENCE CENTRE
INTERNATIONAL STUDENT HOUSE, 229 GREAT PORTLAND STREET,
LONDON, W1W 5PN**

MINUTES

Present

Steven Tsui (ST)

Karen Booth (KB)

Paul Callan (PCa)

Rob Graham (RG)

Clive Lewis (CL)

Sern Lim (SL)

Jacob Simmonds (JS)

Andre Simon (AS)

Sally Rushton (SR)

Lucy Newman (LN)

Chair

Freeman Hospital - Newcastle

Wythenshawe Hospital - Manchester

CTAG Patient Group Co-Chair

Papworth Hospital - Cambridge

Queen Elizabeth Hospital - Birmingham

Great Ormond Street Hospital - London

Harefield Hospital - Middlesex

NHSBT Stats and Clinical Studies, ODT

NHSBT Clinical and Support Services, ODT

Apologies

Nawwar Al Attar (NAA)

Phil Curry (PCu)

Golden Jubilee National Hospital – Glasgow

Golden Jubilee National Hospital – Glasgow

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| 1 | <p>Welcome and introduction</p> <p>ST thanked members for attending the second of the CTAG Heart Allocation Sub Group (HASG). This group was convened to revisit UK heart allocation following the introduction of the three-tier system in October 2016.</p> <p>The revised scheme will be labelled UK Heart Allocation Scheme (2018). The intention is to complete necessary work and present a paper to CTAG in April 2018. Donor age will not be used to determine donor heart allocation. Instead, donor size will be used and this will be defined by donor height.</p> <p>Small Heart Donor: Donor < 145cm in height Standard-sized Heart Donor: Donor ≥145cm in height.</p> <p>As an action from the first meeting, ST wrote to Rob Graham (RG) as Co-Chair of the CTAG Patient Group to nominate an experienced representative as lay perspective for the HASG; the group welcomed RG at the meeting</p> | |
| 2 | <p>Minutes of the HASG Meeting 22nd January 2018</p> <p>The minutes were agreed as an accurate record of the last meeting which took place on 22/01/18</p> | |

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| <p>3</p> | <p>Criteria for Tier 6 +/- Tier 7 The proposed UNOS system will have seven tiers with patients in Tier 6 being ‘all other candidates not listed in Tiers 1-5’ and Tier 7 would be patients who are recognised as ‘inactive’ on the waiting list (i.e. suspended patients).</p> <p>Under the current UK Super Urgent and Urgent Heart Allocation Schemes, there are about 25/30 patients on the waiting list at any time. With the 2018 six Tier system in place, only three to five patients would be listed in each Tier.</p> <p>Patients registered under the NUHAS would go into Tier 6 of the 2018 Heart Allocation Scheme; there would be no Tier 7.</p> <p>The group decided to adopt Tier 1(S) with (S) signifying ‘suspended’ rather than introduce a seventh Tier; this would facilitate improved tracking of the patient if their waiting time is suspended for any reason.</p> <p>Suspended patients will not ‘bank’ time prior to suspension on the waiting list, if a patient is suspended from the waiting list, they can be re-listed in the same Tier once they are well enough. In the past when a patient was suspended from the waiting list, they would then start again at the back of the list according to the chronological date and time of listing. With the new system, the patient would go back into the Tier that they had previously been listed in unless they qualify to be listed in the Tier above or below. With a minimal number of patients in each Tier, the increase in the individuals waiting time once re-listed would be minimised.</p> <p>SR will investigate whether there have been patients in the past who have been listed, suspended and re-listed to establish their outcomes.</p> <p>Following further discussion about the transplant registration form, there is a requirement to tick a box to specify whether the blood group from the donor matched that of the waiting patient as an identical match or a compatible match. Centres have on occasion ticked “identical” inadvertently, thus restricting their recipient’s chances of being offered a donor heart.</p> <p>It was agreed that the option of “blood group identical only” will be removed from the form.</p> <p>This change will be made to the forms, but will take some time to implement.</p> | <p>SR</p> |
| <p>4</p> | <p>Zonal priority for various Tiers Tier 1 – no zonal priority Tier 2 – no zonal priority Tier 3 – zonal priority Tier 4 – zonal priority Tier 5 – zonal priority Tier 6 – zonal priority</p> <p>Patients are to be stratified into tiers based on clinical urgency and the likelihood of survival on the waiting list. Patients are sorted chronologically within each tier. Travel and ischemic time would still need careful consideration since the function of the heart may start to deteriorate after 150 mins of ischemia. Removing zones would potentially lead to increased transport costs and worse outcomes, so zonal priority will still be applied in some tiers. By having more tiers than the 3 currently available in the 2016 UK Heart Allocation Scheme, the shortcomings of zones will be further reduced.</p> <p>The tiers determined at the last meeting were discussed, with the following amendments made:</p> <p>Tier 1 (no zonal priority) a) Patients on ECMO support b) Patients on temporary LVAD, RVAD or BIVAD</p> | |

- c) Imminent risk of dying or irreversible complications, agreed by CTAG Adjudication Panel

Tier 2 (no zonal priority)

Patients requiring Level 3 care in one of the following categories:

- a) Patients with acute endovascular circulatory support devices
- b) Patients on IABP support
- c) Small patients <145cm supported with Berlin Heart Excor
- d) Patients agreed by the Adjudication Panel to justify Tier 2 listing

Tier 3 (zonal priority)

- a) Patients requiring level 2 care and receiving one of the followings:
 - i. a continuous infusion of multiple inotropes
or
 - ii. a single inotrope at high dose defined as
 - dopamine >5ug/kg/min
 - dobutamine >7.5ug/kg/min,
 - epinephrine >0.05ug/kg/min,
 - milrinone >0.5ug/kg/min or adjusted to achieve therapeutic milrinone levels of 100-300 ng/ml (which may correspond to a lower dose in patients with impaired renal function),
 - enoximone >5ug/kg/min.
- b) Hospitalised Implantable LVAD patient and one of the following:
 - i. Recurrent (more than one during this admission), sustained ventricular arrhythmia causing haemodynamic compromise, ICD shocks or requiring external cardioversion despite optimal medical treatment.
 - ii. Refractory VT, VF or Asystole
- c) Hospitalised Implantable LVAD patient with a pump malfunction resulting in failure to deliver effective mechanical support and posing imminent risk to life.
- d) Patient with implantable LVAD pump thrombosis defined as below:
A rise in LDH level \geq x3 upper limit of normal (ULN) occurring after the first 72hrs from implant and associated with two or more of the following:
 - Sustained (>24hrs) Power Elevation of \geq 2W from baseline
 - Clinical evidence of significant haemolysis (haemoglobinuria, hyperbilirubinaemia, haemoglobin drop of \geq 2g/dl)
 - Inability to LV offload (positive RAMP study)
 - New HF symptoms or signs
- e) arrhythmia patients. Refractory arrhythmia (>1 hospital admission over last 3 months with haemodynamic instability or associated with kidney or liver dysfunction)
- f) CHD patients with no option for conventional escalation of therapy – Inpatients unsuitable for inotropes and/or VAD with one of the following:
 - Bilirubin and transaminases >2x ULN
 - eGFR <50ml/min/1.73m², or 20% reduction from baseline
 - requirement for dialysis/CVVH for fluid or electrolyte management
 - recurrent admissions (>3 in last 3 months) with episodes of right sided HF or protein losing enteropathy requiring ascites drainage
 - plastic bronchitis patients
- g) Patients agreed by the Adjudication Panel to justify Tier 3 listing

Tier 4 (zonal priority)

- a) Patient dependent on intravenous inotropes but not fulfilling the criteria of Tier 3.
- b) TAH patient on support for \geq 6 months
- c) Implantable BiVAD patient on support for \geq 6 months
- d) Hospitalised Implantable LVAD, TAH or BIVAD patient with device infection requiring continuous intravenous antimicrobial treatment
- e) Patients awaiting a combined heart/liver transplant

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| | <p>f) Patients awaiting a combined heart/kidney transplant g) Patients awaiting heart and other combined organ transplants h) Patients agreed by the Adjudication Panel to justify Tier 4 listing</p> <p>Tier 5 (zonal priority) a) Implantable BiVAD patient b) TAH patient c) Patients requiring intermittent inotropes or Levosimendan d) More than one hospital admission in preceding 6 months for decompensated heart failure e) LVAD patient with chronic infection needing continuous antibiotics but manageable at home. f) Patients agreed by the Adjudication Panel to justify Tier 5 listing</p> <p>Tier 6 (zonal priority) Heart transplant eligible patients not listed in Tiers 1-5</p> <p>Additional considerations: Each tier may need an adjudication panel sub-category to allow movement through the tier structure for patients not meeting standard criteria.</p> <p>Setting time limits for registration in certain tiers is desirable but administratively difficult.</p> <p>Patients will not be automatically listed on any of the priority tiers within 3 months of a heart transplant. If this is deemed necessary, an application to the CTAG (Heart) adjudication panel should be made.</p> | |
| <p>5</p> | <p>Accepting European Offers European paediatric organ offers are fast track offers on a first come first served basis throughout the whole of Europe. Great Ormond Street Hospital has difficulty responding to the offers in a timely way due to the way their co-ordinators work and feel that they are potentially missing out on these offers. Freeman and Great Ormond Street had an informal gentleman’s agreement regarding the acceptance of such European Organ Offers meaning both teams could accept on behalf of the other. GOS and Freeman ensuring equitable use of these organs – specifically where urgent patients are concerned. This was arranged via a verbal agreement around the time of the CTAG Meeting in Autumn 2015 and recorded in the minutes of: CTAG H(M)(15)2, CTAG Paper (CTAG(15)H17).</p> <p>An official SOP will be agreed and signed to be put in place between Freeman and Great Ormond Street as a documented process; the arrangement will be supported by NHSBT when offering cardiothoracic organs suitable for paediatric recipients.</p> <p>JS will provide a joint letter from GOSH and Freeman to re-confirm this agreement to CTAG and request that this arrangement is formally documented between the two centres</p> | <p>JS</p> |
| <p>6</p> | <p>Combined Heart and Lung Transplants These patients will be prioritised with other patients requiring other combined transplants in Tier 4 unless there are other characteristics that qualify them for Tiers 1-3.</p> | |
| <p>7</p> | <p>Highly sensitised patients Sensitised patients will often wait for an extended time once listed for transplantation and may be disenfranchised for this reason.</p> <p>It was agreed that:</p> <p>a) sensitised patient without any clinical characteristic that qualifies them for Tiers 1-5 will be listed with similar but non-sensitised patients in Tier 6. b) sensitised patient with clinical characteristic(s) that qualifies them for Tiers 1-5 will be listed within the respective Tier but with an adjustment to their listing date to take into account of</p> | |

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| | <p>the median wait for that Tier and their degree of sensitisation e.g. for a patient who qualifies for a Tier with median wait of 30 days and sensitised to 80% of donors, their listing date will be adjusted back by 30 X 0.8 days, i.e. 24 days. During Year 1 of the 2018 Scheme,, median waits for each Tier will be calculated; the adjustments for sensitised patients will be introduced from Year 2 onwards</p> <p>SR will look at data covering the last 5 years establish levels of sensitivity within the cardiothoracic waiting community. The data will be split into MFI≤2k, MFI>2k but <5k, and MFI≤5k or higher.</p> | SR |
| 8 | <p>Criteria for the Ideal Heart Donor</p> <p>Discussion took place at CTAG last year about how many ideal cardiothoracic organs are declined/not used each year. Reasons for declining donor organs should be recorded on the 'reasons for declining donor organs' forms (FRM5722 (Heart)) and (FRM5721 (Lungs)) – however return rates are poor.</p> <p>As part of the drive towards the TOT2020 utilisation of ideal cardiothoracic donor organs must increase. Resulting from this, the Lung Utilisation Group (CTLUG) and Heart Utilisation Groups (CTHUG) have or will be established to report back to CTAG on ideal organs which were unused. The CTLUG has held two useful meetings and have used the ideal lung donor criteria emailed by ST in January. Learnings will be shared by the group and monthly reports will go to the centre directors to facilitate discussion and further feedback to CTAG.</p> <p>The definition of an Standard Heart Donor will be defined as:</p> <ul style="list-style-type: none"> • Donor aged less than 56years • No history of Cardiac Surgery • No history of Cardiac Disease • MAP should not be included • CVP should not be included • Inotropes (dopamine or dobutamine) should be at less than 10µg/kg/min • ECG should be normal • LV wall should be less than 14mm thickness or LVEF should be greater than 45% • Donor has negative viral serology to hepatitis B surface antigen, Hepatitis C Virus and HIV <p>SR will use these criteria to generate a report on ideal heart donors, split by size into one group of under 145cm tall and one group over 145cm tall.</p> <p>Heart utilisation increases as time from death extends, SR will look at how many heart have been utilised with longer than 24 hours since death.</p> <p>Reports and proposals will be taken to TPRC by ST/JyP once ratified by CTAG Wider Group</p> | SR SR ST/JyP |
| 9 | <p style="text-align: center;">Future Meetings</p> <p>Further meetings will be via email/telecon unless another face to face meeting is deemed necessary by the Chair or the group.</p> | |