Approved 26/04/17 **CTAG H(M)(16)2**

NHS BLOOD AND TRANSPLANT
ORGAN DONATION AND TRANSPLANTATION DIRECTORATE

THE EIGHTH MEETING OF THE NHSBT CTAG HEART ADVISORY GROUP ON FRIDAY 14TH OCTOBER 2016, 10:00 – 12:00 AT THE ROYAL COLLEGE OF ANAESTHETISTS, CHURCHILL HOUSE, 35 RED LION SQUARE, LONDON, WC1R 4SG

PRESENT: Mr S Tsui, **Chair**
Mr N Al-Attar, Surgeon, Golden Jubilee Hospital, Glasgow
Dr N Banner, Cardiologist, Harefield Hospital, Middlesex
Ms T Baker, Transplant and Divisional Support Manager, Harefield Hospital
Dr M Burch, Cardiologist, Great Ormond Street Hospital, London
Dr V Carter, BSHI Representative, Newcastle
Mr S Clark, Surgeon, Freeman Hospital, Newcastle
Prof J Dark, National Clinical Lead for Governance, ODT
Prof J Forsythe, Associate Medical Director, ODT
Dr E Jessop, Medical Adviser, NHS England
Ms S Johnson, Director of Organ Donation and Transplantation
Mr M Knight, Lay Member Representative
Dr C Lewis, Cardiologist, Papworth Hospital
Mr J Mascaro, Surgeon, Queen Elizabeth Hospital, Birmingham
Mr J McGuinness, Surgeon, Mater Misercordiae University Hospital, Dublin
Mrs J Nuttall, Recipient Co-ordinator Lead, Wythenshawe Hospital, Manchester
Ms K Quinn, Assistant Director UK Commissioning, ODT
Ms K Redmond, Surgeon, Mater Misercordiae University Hospital, Dublin
Miss S Rushton, Statistician, Statistics and Clinical Studies, NHSBT
Dr R Thomson, Cardiologist, Queen Elizabeth Hospital, Birmingham
Mr R Venkateswaran, Surgeon, Wythenshawe Hospital, Manchester
Ms L Waite, Deputy for Ms L Logan, Regional Manager, Organ Donation Services, ODT
Dr C Wheelans, NSD Scotland (Deputy for Dr M Winter)
Miss E Wong, Statistician, Statistics and Clinical Studies, NHSBT

IN ATTENDANCE:
Miss L Newman, Clinical & Support Services, ODT
Mrs K Zalewska, Clinical & Support Services, ODT

APOLOGIES: Dr M Al-Aloul, Cardiologist, Wythenshawe Hospital, Manchester
Mr J Asher, Clinical Lead – Medical Informatics (ODT)
Dr M Carby, Chest Physician, Harefield Hospital
Prof S Fuggle, Scientific Advisor, ODT
Mr B Hume, Assistant Director TSS, ODT
Dr S Lewis, Acting Medical Director, Welsh Health Specialised Services
Ms L Logan, Regional Manager, Organ Donation Services, ODT
Dr P Mangat, Acting Medical Director, Welsh Health Specialised Services
Dame J McVittie, Lay Member Representative
Mr N Muthialu, Surgeon, Great Ormond Street Hospital (Deputy for Dr H Spencer)
Dr J Parmar, Chest Physician, Papworth Hospital, Cambridge
Dr Z Reinhardt, Freeman Hospital, Observer
Mrs C Riotto, Recipient Transplant Co-ordinator Representative, Papworth Hospital
Ms D Russell, General Manager, Harefield Hospital, Observer
Ms A Sheldon, Head of Referral & Offering, ODT
Mr A Simon, National Clinical Lead for Organ Utilisation, Harefield
Dr H Spencer, Surgeon, Great Ormond Street Hospital
Mr M Stokes, Duty Office Services Manager, NHSBT

Ms H Tincknell, Lead Nurse, Recipient Co-ordination
Dr J Townend, Cardiologist, Queen Elizabeth Hospital, Birmingham
Ms S Watson, Commissioner, NHS England
Dr M Winter, (NSD) National Services Division - Scotland

	Apologies and welcome	**Action**
1	**DECLARATIONS OF INTEREST IN RELATION TO THE AGENDA - CTAG(16)H12** There were no declarations of interest in relation to the agenda	
2	**MINUTES OF THE MEETING HELD ON WEDNESDAY 13TH APRIL 2016 - CTAG H(M)(16)1**	
2.1	**Accuracy** The minutes of the last meeting were agreed as a correct record	
2.2	**Action points - CTAG H(AP)(16)1** **AP1 –** S Rushton will liaise with IMACS via Stephan Schueler regarding the data fields collected on IMACS but not in the UK VAD database and report back to S Tsui to make a decision about whether to prioritise this project. **AP2 – Heart incidents for review – Clinical Governance report** This work has been completed **AP3 – DCD Heart Retrieval Service Evaluation** The CTAG DCD Heart working group generated a report which has been fed back to the overarching NHSBT DCD Heart Steering group. **AP4 – Amendments to urgent heart scheme –** The go live date for the new Super Urgent and revised Urgent Heart Allocation Schemes is 26th October 2016. S Tsui reiterated the need for centres to re-validate those on the current UHAS by completing the new registration form. These were emailed to centres and a deadline of 3 weeks was given for them to complete this process. To date 4 patients have been registered and the final date for this work to be completed is 19th October 2016. Patients who have not been registered on the new SUHAS or the revised UHAS will automatically revert to the non-urgent waiting list. **AP5 – Access to heart transplantation for larger paediatric patients at GOSH** M Burch reported that the first patient from GOSH listed on the Harefield waiting list had gone very smoothly. This arrangement will continue to be monitored. **AP6 – GOSH 20cm donor-recipient size match rule** A review of this rule has been deferred in light of the changes in AP5 above. **AP7 – Prolonged heart registrations** This would not be reviewed until the changes have taken place at AP4 above. **AP8 – Updated post-heart transplant survival models** NHSBT is not currently identifying or separating OCS data from other data collected. The “ischemia times” being reported by Harefield include the OCS duration and these are skewing the data as the NHSBT database does not include a field for OCS. J Mehew had removed ”ischaemic time” as a risk factor from her analysis, but the group felt it was important to include “ischaemic times” as this has consistently been shown to affect 30-day survival. Following discussion, it was decided that rather than removing the ischemia time for all centres, it would be better to remove Harefield patients who had OCS heart transplants from the	**S Rushton** **Clinical Reps**

	analysis so that the "ischaemic time" data can still be included for all other UK patients. This change would be included for the next Cardiothoracic Annual Report. S Rushton to look into how best to carry out this analysis. R Johnson has already done some work on the data fields for perfused organs, and will be taking a paper to RINTAG in November and then to the next AG Chairs meeting.	**S Rushton**
2.3	**Matters arising, not separately identified** There were no further matters arising.	
3	**GOVERNANCE ISSUES**	
3.1	**Non-compliance with heart allocation** There were no instances of non-compliance to report.	
3.2	**Heart incidents for review** There has been no increase in the number of heart incidents recorded since the new NORS rota was introduced. There were 4 extended retrievals, due in part to SNODS calling teams too early and the Duty Office not knowing which team to mobilise.	
3.2.1	**Clinical Governance report - CTAG(16)H13** J Dark reported on clinical governance incidents relating to hearts: • Damage due to rapid cross clamp • Delayed transplant as awaiting test results on donor who may have come into contact with the Zika virus • Delayed offering process due to one centre accepting two offers then deciding they could not undertake both transplants within the required timespan This incident highlighted the need to review timings within the overall process. Some delays may be due to poor decision making and initially accepting organs which are later declined. J McGuiness added that some surplus donor hearts from Northern Ireland could be utilised in the UK if arrangements could be made with a centre close to an airport in the UK. S Clark suggested the issue of a twice yearly newsletter to transplant teams as a platform for making centres aware of any issues which would also be discussed at CQUIN. Website reports such as cautionary tales are useful and can be disseminated within centres, but these contain few recommendations as to how things could have been done better. J Dark and J Forsythe to look at how to take this suggestion forward, including the inclusion of organ specific reports. C Wheelans asked whether this would be picked up as part of the work on donor characterisation and offered to collaborate on this work with J Dark.	**J Dark** **J Forsythe** **J Dark** **C Wheelans**
3.3	**Summary of CUSUM monitoring of 30 day outcomes following heart transplantation - CTAG(16)H143** There were no signals in the last six months. J Forsythe highlighted an incident involving an error with virology results in a donor which ultimately resulted in the death of a recipient. Blood samples were taken and tested negative for CMV. Three centres accepted and transplanted organs from this donor. Two of the three centres re-tested the donor blood sample which was positive for CMV, treated their recipients locally for CMV, but	

	failed to share this information with the Duty Office or the third centre. This resulted in a missed opportunity. All centre directors were asked to remind their teams about the importance of reporting transplant related incidents so that other centres can act on this information.	**Centre Directors**
3.4	**QUOD Specimen collection – CTAG(16)H15** QUOD Papers will be circulated after this meeting. (**Post meeting note** – papers were circulated by L Newman on 18/10/16). NHSBT supports QUOD, a project to collect specimens from kidney and liver donors, and which has captured specimens from over 1500 donors. Hearts and lungs have not been included in specimen collection until now. J Dark had drafted a proposal to take to the QUOD meeting in November to introduce cardiothoracic specimen collection from adult donors. At this stage there would be no additional cost, and just a small amount of paperwork which could be used as a resource in future. Although the CTAG Clinical Audit group supports the project in principle there were concerns that tissue collection for possible future projects was not appropriate. J Dark explained that a patient information leaflet would be given to patients informing them that biopsies are taken from all donated organs. • S Tsui asked whether it is ethical to give the information in written form but not verbally. • R Venkataswaren has been involved with a trial where donor families were happy to consent to donor management, but were reluctant to sign up to have biopsies taken. • During that trial only a few families had asked questions; all of the information about the biopsy was contained within the information sheets. • It is proposed that where the cardiothoracic team is involved with the retrieval they will carry out the biopsy; however, if the heart is not being explanted, the abdominal teams will be able to take the specimen and send it with the blood and urine samples from the kidney and liver. • There may be issues such as bleeding but these will be monitored over the first 12 months. A trial was conducted in Birmingham, and there were no instances of bleeding from the biopsy site. • N Al-Attar raised the importance of quality control of the specimen collection. Timing is essential in order to prevent any increase to ischemia time. If the heart is being explanted then the sample should be taken as the explant happens, however if the heart is remaining in situ then the biopsy can be taken sooner in the process. • The process must be able to provide tangible results to report to the retrieval teams for it to be of any benefit. • From a QA point of view, there would be little point in collecting samples and then leaving them unused for a considerable length of time before realising that they have been taken from the wrong place or are the wrong type of tissue. • The possibility of the biopsy resulting in damage to the donor organ was acknowledged. Any repair to a hole caused by the biopsy may not be picked up until the donor organ has been implanted. J Dark confirmed that QUOD has a robust process for picking up problems with kidney biopsies. It was noted that the biopsy of the specimen could increase the ischemia time following organ explant, which the proposal may be challenged on, particularly if it is only increased to satisfy the requirements of the tissue bank. CTAG members agreed in principal to the proposal, but asked to see a tangible research project with evidence that this is of value. N Al-Attar suggested starting with declined hearts to promote the project initially in order to allay concern.	**J Dark** **L Newman**

	Comments should be returned to J Dark by the 31st October in order for him to summarise to take to QUOD on 21st November.	**Clinical Reps**
4	**Report from Chair – CTAG(16)H16** We have strengthened the core group telecons over the past 12 months. DCD heart study results so far: • Harefield have carried out 4 DCD heart transplants with 3 long term survivors • Papworth have carried out 23 DCD heart transplants with 22 long term survivors • Manchester applied to start the DCD programme in 2015 and were advised to gain experience using the OCS machine with DBD heart retrievals. Following updated training for CLODs and SNODs and informing recipients, it is hoped that Manchester can go live on 5th December 2016. S Tsui confirmed that NHSBT will provide support for donor offers, transport costs and retrieval teams, but the teams themselves need to fund the use of the OCS	
5	**Update on Super Urgent Heart IT Project** To be updated during the Shared section of the meeting	
6	**VAD Update** E Jessop explained that NHS England currently funds bridge to transplantation VADs only. Whilst it may be unlikely that destination VADS will be commissioned depending on cost, NHS England has suggested that a Provisional Policy Proposal for DT is submitted. S Tsui has been asked to act as the Clinical Policy Lead to coordinate this process. S Tsui will circulate the necessary paperwork to Centre Reps to review the fields, and comments should be returned by 31st October at the latest. VADs use appears to vary between centres, so the plan is to look at differences in the current criteria. It might be necessary to move towards a CTAG panel where there might be questions about the appropriateness of certain bridge to transplantation VAD implant when there is no realistic chance of a transplant. S Tsui stated that 85% of heart transplants in the UK are for patients on the urgent waiting list. The use of VADs improves the clinical outlook for unstable patients. Once supported with a VAD, they improve and may have to remain on the non-elective waiting lists for extended periods of time. Members were advised of referrals of patients from Wales who were sent to centres in England for transplant assessment. In one case, when the decision was made by the centre to implant a VAD, funding was initially refused. The patient was referred back to Wales for palliative care before Welsh commissioners agreed to fund the treatment and the LVAD implant went ahead. These cases leave a patient in a high dependency bed whilst commissioners make a decision. Of particular concern is the movement of sick patients between centres whilst funding decisions are being made. The Trusts involved have sought legal guidance on this situation. E Jessop added that the NHS England legal viewpoint would be that centres in England are under no obligation to treat patients from another nation. NHS England has a contract with Wales for transplantation, but not for mechanical support devices. M Burch asked for clarity regarding a three year old paediatric referral patient from	**S Tsui Centre Directors** **Centre**

	Cardiff requiring a Berlin Heart. J Forsythe requested that each centre liaise with S Tsui, who in turn will contact Sian Lewis from the Welsh Commissioning Board for clarity.	**Directors S Tsui**
6.1	**VAD Reporting Audit – CTAG(16)H17** There are some data discrepancies between NSD Scotland/NHS England and NHSBT, therefore the Annual VAD Report has not been published yet. S Tsui confirmed that the counting of the procedures and devices differs; the details required in both reporting mechanisms are the same. N Banner commented that the VAD report shouldn't be held up for too long as it contains important information which clinicians need to know. S Watson would like to look at the data and understand the reasons for the lack of correlation. The process of data collection needs to be looked at in parallel. Each centre representative to take a copy of the report and check on discrepancies in their data and report their findings back to S Rushton before 1st December. This should allow the report to be published early in the New Year.	**Centre Directors S Rushton**
7	**STATISTICS AND CLINICAL STUDIES REPORT**	
7.1	**Urgent Heart Allocation Scheme Activity – CTAG(16)H18** This paper compares the allocation activity in the current financial year with the last financial year. In future this report will incorporate the urgent and super urgent categories. S Tsui suggested using this report in the future to try to establish whether patients are being actively removed from the waiting lists once they have received a VAD. S Tsui commented that the requirement in Paragraph 9 of the policy was removed some time ago and should be removed from the document.	**S Rushton**
7.2	**Clinical Characteristics of Urgent Patients – CTAG(16)H19** This report includes a breakdown of urgent patient registrations by category. Non reported information includes forms not being returned, and forms returned with incorrect or unlisted categories. In addition, 14% of patients were on mechanical or balloon pump support, these patients would now be listed on the super urgent scheme. As per the registration policy, supporting evidence from the Adjudication Panel need to be sent to the Duty Office for patients to be listed.	
7.3	**UK Fast Track Scheme: Hearts – CTAG(16)H20** A report on the heart fast track scheme indicated that 33 hearts were offered to 184 centres in the last two years, of which 6 were accepted and 3 transplanted. J Dark mentioned a governance incident where there was some confusion in the Duty Office over the order of offering to urgent and non-urgent patients. S Rushton confirmed that when the new system goes live on 26th October acceptance will be on a first come first served basis.	
8	**Any Other Business** There were no other items of business	
9	**Dates of 2017 meetings:** Wednesday 26th April 2017 – 3pm-5pm, London Venue TBC Wednesday 13th September 2017 – 10am-12noon, London TBC	