

**NHS BLOOD AND TRANSPLANT  
CARDIOTHORACIC ADVISORY GROUP  
CLINICAL AUDIT GROUP: CHAIRMAN'S REPORT APRIL 2018**

**SUMMARY**

- 1 This paper provides an overview of the work of the CTAG Clinical Audit Group since the last CTAG meeting in September 2017. It is also my last report as the Chair of CTAG CAG. I am grateful to the Audit Group members together with Sally Rushton and her colleagues in NHSBT Statistics and Clinical Studies for their work and to Lucy Newman for administrative support.

**INTRODUCTION**

- 2 The Group has welcomed three new members: Marius Berman, elected as Donor Management and Organ Retrieval representative; Katie Morley, elected as Allied Health Professional representative and Margaret Harrison (CTAG Lay Member representative). All three attended their first face to face meeting in January 2018.

The position of Lung Transplant Representative will be due for election in the autumn. The incumbent, Dr Richard Thompson, is eligible for re-election.

- 3 The Clinical Audit Group held our first face-to-face meeting of the year in Birmingham in January. We held a teleconference in March and plan to have a second face-to-face meeting in June followed by another teleconference in September. Additional telecons will be arranged when necessary. The attendance of members at CAG meetings will be reported annual for the Autumn CTAG meeting.

**CLINICAL AUDIT FELLOWS**

- 4 Summaries of the work carried out by Aravinda Page (NHS England Clinical Fellow) and Sanjeet Singh (NHS Scotland Clinical Fellow) are provided in the **Appendix A**. Both Fellows are coming to the end of their term of appointment.

CTAG is now in a position to look at appointing new Fellows, NHS England funding has been confirmed for this. Rachel Johnson (RJ) and John Forsythe (JF) wish discuss and align audit priorities related to the CT Workplan, in collaboration with JyP as incoming CTAG Chair. The new Fellow(s) will be affiliated members of the Cardiothoracic Audit Group and CTAG and would be directly accountable for their work. The CAG feels strongly that the process for recruitment should be competitive and based on proposed Audit and Research projects. Candidates must be given the opportunity to register for a Higher Degree and to gain clinical experience to support a career path in Cardiothoracic Transplantation

**DATA APPLICATIONS**

- 5 There have been three new external applications for data which were emailed to members for their comment and approval.

**Shapey** - Manchester Royal Infirmary processed an application relating to insulin therapy being used in donors/recipients recruited to the QUOD Bank:

*7 days for Group approval*

**Freystaetter** - Freeman Hospital processed an application relating to recipient lung size mismatching outcomes post-transplant:

*7 days for Group approval*

**Merrick** - Public Health England processed an application relating summary data of new registrations to the lung transplant list, lung donors and lung transplants completed per financial year (2005-2017), stratified by Strategic Health Authority:

*<1 day for Group approval (the request arrived at the time of a CAG meeting).*

There has been a re-application for data from Professor Dark. The project was approved previously and the further data request is being handled by NHSBT Statistics

### NHSBT ORGAN SPECIFIC REPORTS

- 6 The NHSBT Annual Cardiothoracic Organ Specific Report was published in September 2017, the report can be found on the ODT Clinical Website: [Cardiothoracic Annual Activity Report 2017](#)

The NHSBT Annual VAD Report, now called the Annual Report on Mechanical Circulatory Support related to Heart Transplantation, was published in January 2018 and can be found on the ODT Clinical Website: [MCS Annual Report 2018](#)

### CHAIRMAN'S PERSPECTIVE

- 7 This is the 6<sup>th</sup> year of the CAG in its present format and the end of my term as its Chairperson. During this time, the group has been expanded to include representatives from all clinical areas of cardiothoracic transplantation. The group has become more dynamic following arrangements for regular elections and a turn-over of representatives. New blood has helped to generate new ideas and project proposals. The regular reports to CTAG have increased the transparency of the CAGs activities.

Progress should be assessed in light of the fact that we are an advisory group with no staff or budget. Our work depends on the goodwill of the group's members and our colleagues. We are grateful for the expert support of the NHSBT statistics team. Our members and the statistics team have many other demands on their time; this sometimes means that worthwhile projects take longer than we would like to reach a conclusion. I am pleased to report that several of our ongoing projects have now reached completion and most of the others will soon do so (**Appendix B**). Also, both of the Clinical Audit Fellows have been highly productive (**Appendix A**). In 2018, we have the exciting prospect of initiating new Audit Group studies and appointing new Audit Fellows.

A continuing frustration has been the difficulty in modifying and updating the databases on which our Audit and Research work depends. I am pleased to report that at a recent meeting with Edmund Jessop and Sarah Watson from NHS England, it was agreed that there should be an annual meeting between the Chair and other representatives of the CAG, NHS England and NHSBT to discuss Audit priorities and plans for the year's Annual Reports. NHS England agreed that they have an important role in ensuring adequate resources are made available to maintain and update the Transplant Databases, managing the process through their contract with NHSBT. JyP will liaise with Sarah Watson to move the plans forward.

One particular issue has been the need to revise the Mechanical Circulatory Support database to improve its user-friendliness and adapt it in a period of rapid technological change and, consequently, in clinical practice. Again, I am pleased to report that NHS England have agreed to support this process and manage the stewardship of the MCS database through its relationship with NHSBT.

Overall the CAG is in good health, with a dynamic membership together with a continuing flow of new ideas and projects. It continues to adapt to our changing clinical, technological and organisational environment.

### UPDATING THE MECHANICAL CIRCULATORY SUPPORT (LVAD) DATABASE

- 8 NHS England agreed to fund necessary alterations to the VAD Database at a meeting with Sarah Watson and Edmund Jessop on 7<sup>th</sup> February; this will allow the UK to continue to collect its own data and, as previously agreed, to collaborate with the relevant International databases (EuroMACS and IMACS)

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SR will hold a working group meeting in ODT (Organ Donation and Transplantation) in Bristol to start planning required alterations to the existing database. Attendees would represent each centre and include clinicians and VAD coordinators (the VAD coordinators enter data directly into the Database) together with IT and Data Managers from ODT.

**CTAGS(18)13****UPDATE ON AUDIT PROJECTS**

- 9 Progress reports from project leaders and project proposals from members are detailed in **Appendix B**.

**Nick Banner**  
**CTAG Audit Chair**

**MARCH 2018**

**APPENDIX A**  
**CTAG CLINICAL AUDIT GROUP - CLINICAL AUDIT FELLOWS REPORTS**

**Name:** Aravinda Page  
**Supervisor:** Steven Tsui  
 Royal Papworth Hospital, Cambridge

**Progress report – March**

Stream One: Scout Project Phase II

I have been involved with the Scout Project Working Group in refining the data collection for the second phase of the scout project. One of the big challenges we have faced in Phase II was incomplete data. However, with the data collected we were able to present the data set to external reviewers to guide the inclusion of scouting as part of the National Organ Retrieval Service.

**Stream Two: Advanced optimisation of poorly functioning donor hearts**

Together with my supervisors we have designed an experimental protocol to investigate the effect of circulatory support in optimising poorly functioning donor hearts. This research protocol investigates two aspects, firstly, the use of extra corporeal membrane oxygenation (ECMO) in the brain dead donor in an attempt to offload the donor heart and allow for a period of recovery while limiting the use of deleterious pharmacological support. Secondly, the protocol investigates the effect of normothermic machine perfusion compared to cold storage. The novel strategy we propose will combine these two circulatory support technologies to allow poorly functioning donor hearts a chance to recover, as well as minimize the ischaemic insult sustained as a result of the retrieval process.

We were successful in being awarded the Heart Research UK grant for New and Emerging Technologies to the value of £249,612 (Grant Reference: RG2654/16/18) and receiving further support from industry (Maquet) with regards to provision of equipment for research. We successfully submitted for a project license at the Royal Vet College in London and have now also applied to include the University of Cambridge animal facility at the Barcroft Centre where we start work on 6<sup>th</sup> April 2018. This will allow us better access to the animal work to ensure that the work can be completed promptly. The pilot work for this has been carried out using abattoir hearts that has enabled us to develop a portable ex-situ perfusion rig for isolated heart perfusion in research.

This proposed work and grant also formed the basis of a successful application to register for a PhD with the Department of Surgery at the University of Cambridge.

**Courses and Conferences**

I was one of the organisers for the Cambridge DCD Heart Symposium which was held in September 2016 in Cambridge. We were successful in receiving accreditation from the Royal College of Surgeons of England for this event and were kindly sponsored by TransMedics (<http://www.dcdheart.com/>)

30<sup>th</sup> European Association for Cardio-Thoracic Surgery Annual Meeting, October 2016 (Barcelona) - Heart transplantation from donation after circulatory determined death (*oral presentation*)

2<sup>nd</sup> European Cardio Thoracic Transplant Association Meeting (European Society of Organ Transplantation), October 2016 (Barcelona) - Can ECMO contribute to improve the pool of thoracic organ donors? (*oral presentation*)

37<sup>th</sup> International Society of Heart and Lung Transplantation Annual Meeting 2017 (San Diego)

1. Does the assessment of DCD donor organ hearts on OCS using lactate need redefining? (*oral presentation*)
2. Ischemic reperfusion injury and allograft rejection following DCD heart transplantation: early results. (*oral presentation*)

18<sup>th</sup> Congress of the European Society of Organ Transplantation), September 2017 (Barcelona) – Combined Transplantation: A case-report of the world's first heartkidney transplant from donation after circulatory determined death (*oral presentation*)

31<sup>st</sup> European Association for Cardio-Thoracic Surgery Annual Meeting, October 2017 (Vienna) – Does DCD heart retrieval affect other solid organ utilization? (*oral presentation*)

38<sup>th</sup> International Society of Heart and Lung Transplantation Annual Meeting 2018 (Nice)

1. Changing Trends in Acceptance Criteria for Cardiac Donors: 15 Year UK Experience (*oral presentation*)
2. Early Outcomes from DCD Heart Transplantation: A Single Centre Experience (*oral presentation*)
3. DCD Heart Retrieval Does Not Compromise Other Donor Organs: The UK Experience (*mini-oral presentation*)

Authors	Title	Publication
Barbero, C; Ravaglioli, A; Page, A <i>et al</i>	Retrieval Team Initiated Early Donor Management (Scouting) Increases Donor Heart Acceptance Rate for Transplantation	The Journal of Heart and Lung Transplantation; 2016;35(4);S220
Page, AA; Messer, S; Tsui, SS; Large, SR;	Early results using donation after circulatory death (DCD) donor hearts	Current Transplantation Reports; 2016;3(3);199206
Page, A; Messer, S; Axell <i>et al</i>	Does the Assessment of DCD Donor Hearts on the Organ Care System Using Lactate Need Redefining?	The Journal of Heart and Lung Transplantation; 2017;36(4);S16-17
Page, A; Goddard, M; Messer, S <i>et al</i>	Ischaemic Reperfusion Injury and Allograft Rejection Following DCD Heart Transplantation: Early Results	The Journal of Heart and Lung Transplantation; 2017;36(4);S122
Messer, S; Page, A; Axell, R <i>et al</i>	Excellent Early Outcomes Following Heart Transplantation from Circulatory Dead Donors	The Journal of Heart and Lung Transplantation; 2017;36(4);S15-16
Pavlushkov, E; Page, A <i>et al</i>	Post-Transplant Assessment of DCD Cardiac Allografts with MRI	The Journal of Heart and Lung Transplantation; 2017;36(4);S46-47
Page, A; Messer' S <i>et al</i>	Heart transplantation from donation after circulatory determined death	Annals of Cardiothoracic Surgery ( <i>in press</i> )

**Name:** Sanjeet Avtaar Singh  
**Supervisor:** Nawwar Al-Attar  
 Golden Jubilee National Hospital, Glasgow

### **Progress report – March 2018**

Sanjeet Singh is in his final year as a CTAG Audit fellow. He has completed both cycles of data collection and is writing up his thesis for Primary Graft Dysfunction(PGD) for hearts in the UK.

With Sally Rushton's help, he has validated the working model of PGD in the UK. A multivariable model predicting PGD was formulated based on the audit data collected with assistance from NHSBT as part of the national audit on PGD.

He has filled in an application for data on abdominal organs to ascertain if PGD occurring in one organ has an impact on other organs retrieved from the same donor. He will be working with another NHSBT fellow, Dr Patrick Trotter for this project. No study incorporating the new ISHLT Defined PGD in hearts has been done to note the impact on other retrieved organs.

After a teleconference with Dr Nicholas Banner, Ms Sally Rushton, Prof Nawwar AlAttar and Prof Stephen Clark, it was agreed that Sanjeet would look at long term outcomes after moderate/severe PGD in the UK going back to 2007 (10-year data).

Sanjeet was a semi-finalist in the Young Investigator of the Year Award (EACTS) 2017 with his abstract titled 'Mechanical circulatory support for post-acute myocardial infarction with refractory cardiogenic shock – A decade of lessons'

He served as an abstract reviewer and has also been invited to co-chair a session at ISHLT in Nice, France.

### **Summary of Presentations**

2018 International Society of Heart and Lung Transplantation (ISHLT) Annual Meeting, April 2018

Novel Technique to Reduce Warm Ischemic Time During Cardiac Implantation (Poster) K. Morcos, S. Singh, S. Das De, H. Al-Haideri, Y. Hegazy, J. Dalzell, S. Nair, H. Doshi, N. Al-Attar, P. Curry

Donor Right Ventricular Stroke Work Index (RVSWI) is a poor predictor of Primary Graft Dysfunction (PGD) after heart transplantation. (Poster) Sanjeet Singh Avtaar Singh, Sudeep Das De, Jonathan Dalzell, Harikrishna Doshi, Philip Curry, Nawwar Al-Attar, Sukumaran Nair

Validation of a model to predict Primary Graft Dysfunction (PGD) after adult heart transplantation in the United Kingdom (Mini-Oral) S. Avtaar Singh, N. R. Banner, S. Rushton, C. Berry, N. Al-Attar

The impact of gender mismatch on survival in heart transplantation (Poster) S. Avtaar Singh, S. Das De, C. Berry, N. Banner, N. Al-Attar

2018 Society of Cardiothoracic Surgeons (SCTS) Annual Meeting, March 2018

Donor Right Ventricular Stroke Work Index (RVSWI) is a poor predictor of Primary Graft Dysfunction (PGD) after heart transplantation (poster) Sanjeet Singh Avtaar Singh, Sudeep Das De, Jonathan Dalzell, Harikrishna Doshi, Philip Curry, Nawwar Al-Attar, Sukumaran Nair

Validation of a model to predict Primary Graft Dysfunction (PGD) after adult heart transplantation in the United Kingdom (Oral) S. Avtaar Singh, N. R. Banner, S. Rushton, C. Berry, N. Al-Attar

The impact of gender mismatch on survival in heart transplantation (Oral) S. Avtaar Singh, S. Das De, C. Berry, N. Banner, N. Al-Attar

The Role of Mechanical Circulatory Support (MCS) as a Bridge to Decision in Cardiogenic shock (CS) after ST-Elevation Myocardial Infarction (STEMI) at a National Referral Centre (Oral) S. Avtaar Singh, S. Das De, A. Sinclair, J. Dalzell, C. Berry, P. Curry, H. Doshi, N. Al-Attar, S. Nair

2017 European Association of Cardiothoracic Surgery (EACTS) Annual Meeting 2017

Mechanical circulatory support for post-acute myocardial infarction with refractory cardiogenic shock – A decade of lessons (Oral) S. Avtaar Singh, S. Das De, A. S. Avtaar Singh, S. Das De, Al-Aldhami, Y. Hegazy, A. Sinclair, J. Dalzell, C. Berry, P. Curry, H. Doshi, N. Al-Attar

2017 International Society of Heart and Lung Transplantation (ISHLT) Annual Meeting, April 2017

The incidence and outcome of Primary Graft Dysfunction after adult heart transplantation in the United Kingdom. (Oral) S. Avtaar Singh, N. R. Banner, S. Rushton, B. Mahesh, A. Simon, C. Berry, N. AlAttar.

The Post- Operative Glasgow Transplant Score (Poster) S S Avtaar Singh, T Vassalos, F Nolan, J Sharp, A Young, D Young, N Al-Attar

2017 Society of Cardiothoracic Surgeons (SCTS) Annual Meeting, March 2017

The incidence and outcome of Primary Graft Dysfunction after adult heart transplantation in the United Kingdom. S. Avtaar Singh, N. R. Banner, S. Rushton, B. Mahesh, A. Simon, C. Berry, N. AlAttar.

The Post- Operative Glasgow Transplant Score S S Avtaar Singh, T Vassalos, F Nolan, J Sharp, A Young, D Young, N Al-Attar

Published Abstracts The Incidence and Outcome of Primary Graft Dysfunction After Adult Heart Transplantation in the United Kingdom. Singh SA, Banner NR, Rushton S, Al-Attar N. The Journal of Heart and Lung Transplantation.36(4):S146-S7.

A Pilot Evaluation of the Post-Operative Glasgow Transplant Score (Post-GTS tm) for Heart Transplants. Avtaar Singh S, Vassalos T, Nolan F, Sharp J, Young AM, Al-Attar N. The Journal of Heart and Lung Transplantation.36(4):S398-S9.

### **Full Publications**

Singh SSA, Das De S, Spadaccio C, Berry C, Al-Attar N. An overview of different methods of myocardial protection currently employed peri-transplantation. Vessel Plus; Vol 1, No 4 (2017). 2017.

Capoccia M, Avtaar Singh S, Hegazy Y, Sinclair A, Al-Attar N, Mahesh B. Rescue Levitronix Centrimag as a bridge to decision: is it still worthwhile? Indian Journal of Thoracic and Cardiovascular Surgery. 2017;33(4):303-8.

Singh SSA, Banner NR, Rushton S, Simon A, Berry C, Al-Attar N. ISHLT Primary Graft Dysfunction incidence, risk factors and outcome: a UK National Study, Transplantation (Accepted for publication)

Case Reports Singh SSA, Capoccia M, Deep K, Al-Attar N. Sternal malunion fixation using a Titanium Sternal Fixation System in a diabetic patient. The first of its kind in Scotland. Vessel Plus. 2017;1(4):242-5.

Avtaar Singh S, Capoccia M, Al-Attar N. Dealing with the Unexpected but Chasing the Inevitable: Atrio-Ventricular Disruption Following Aortic Valve Replacement in an Elderly Patient. Clin Surg. 2017; 2: 1402.

Books Myocardial Protection in Cardiac Surgery. Avtaar Singh, S., Das De, S. and Al-Attar, N. (2017). LAP LAMBERT Academic Publishing ISBN-13: 978-3330337084

Patient Satisfaction in Enhanced Recovery after Thoracic Surgery. Graham, K., Avtaar Singh, S. and Kirk, A. (2017). LAP LAMBERT Academic Publishing. ISBN-13: 978-6202004831

## APPENDIX B CLINICAL AUDIT GROUP – PROJECT REPORTS AND PROPOSALS

### ACTIVE PROJECTS

1. **BTC VAD Project – Steven Shaw (SSh)**

The BTC project is now complete. The study will be presented at ISHLT and the manuscript has been submitted to the *European Journal of Cardiothoracic Surgery*, currently pending review

2. **Long-Term VAD Outcomes – Jayan Parameshwar (JyP)**

The LTVAD project has been finalised. SR has created creating a poster to be presented at ISHLT. The manuscript has also been submitted to *Heart*.

3. **Outcomes from listing for lung transplantation – Jasvir Parmar/Richard Thompson (JsP/RT)**

The outcomes from listing for lung transplantation manuscript has been submitted to *Thorax* and has been commented on by reviewers, requiring some modifications and further statistical detail. Jenny Mehew (JM) and Rachel Hogg (RH) are working on this.

4. **PGD Study**

The CAG has decided to discontinue this project.

### COMPLETED PROJECTS

1. **Congenital Heart Disease Project – Mike Burch (MiB)**

The manuscript has been submitted to *Journal of Heart and Lung Transplantation*. Reviewers comments on the manuscript are expected soon

2. **Effect of Ischemia Time on Post Lung Transplant Survival – John Dark (JD)**

Jenny Mehew (JM) has agreed to work with John Dark (JD) to finish this work. This work is not on the current Statistical Team work stream for CAG

3. **Interval between Brain Stem Death to Organ Retrieval – Rajamiyer ‘Venkat’ Venkateswaran (RV)**

The manuscript from this project has been published in the *European Journal of CardioThoracic Surgery*.

### PROPOSED PROJECTS

1. **HGS Study Proposal – Nawwar AIAttar (NAA)**

The HGS Study project looks at the **Hand Grip Strength** to assess the frailty of patients/recipients and the subsequent outcomes of heart transplantation in relation to frailty. There are other indicators to frailty and social deprivation, however, hand grip strength is relatively easy to measure with minimal impact and cost to centres. Glasgow, Manchester Harefield and Papworth have identified their local HGS champions, other centres will be asked to do the same. This is the first study of this kind in the field, and its hoped that it will provide some useful insights

2. **Ongoing S/ULAS Audit Work – Richard Thomson (RT)**

RT is interested in a project to look at the impact of the new lung allocation schemes. The new allocation schemes were implemented in May 2017, and initial data will be presented at ISHLT next week. SR will circulate the slides for ISHLT to the CTAG lung representatives so they can see the preliminary analysis

3. **MCS – HM3 (L)VAD Project Proposal Steve Shaw/Rajamiyer ‘Venkat’ Venkateswaran (SSh/RV)**

SSh proposed a project in collaboration with Sern Lim (SL), Birmingham, to study outcomes for **Heart Mate 3** patients. Manchester and Birmingham both use HM3, and good cohort has been recruited. Patients will be reviewed at the first year, to assess whether HM3 performs better and offers better survival than HM2 in the UK, and will also look at whether the HW performs better than the HM2 or HM3. We will delay the start of this project until Summer 2018 when it can be added to the workplan for the Statistics and Clinical Studies Team. SSh and JyP will approach each UK centre for a study representative.



4. **Paediatric Project Proposal – focus on re-implantation of hearts and lungs in paediatric patients - Zdenka Reinhardt (ZR)**  
Paediatric project to be discussed at CAG meeting in June in June
5. **Retrieval Project Proposal – Marius Berman (MaB)**  
MBe is working with QUOD and plans to lead a project looking at hearts which may have been falsely declined due to Coronary Disease. The study will include all transplant centres. Some clinical features may be misinterpreted as Coronary Disease, MBe will be meeting with Rutger Ploeg before moving the project forwards, and hope to be in a position to discuss it at the next CTAG meeting. MBe will have a proposal ready for the next meeting in June.
6. **Allied Health Professional Project Proposal – Katie Morely (KM)**  
KM has proposed a project to look at the perception of the Donor Case Practitioners in the donor pathway  
KM will bring the project proposal to the CAG meeting in June.