NHS BLOOD AND TRANSPLANT
CARDIOTHORACIC ADVISORY GROUP
CLINICAL AUDIT GROUP: CHAIRMAN'S REPORT SEPTEMBER 2019

SUMMARY

This paper provides an overview of the work of the CTAG Clinical Audit Group (CTCAG) since the last CTAG meeting in February 2019, and my third report as the Chair of CTAG Clinical Audit Group. 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

The Group welcomed two new members at the most recent meeting. Gill Hardman (ST6 Cardiothoracic Surgical Trainee) has joined us from Newcastle as the Cardiothoracic Clinical Audit Fellow for the next three years. This will be the first time that the Clinical Fellow has become an active member of the Clinical Audit Group, and we look forward to working closely with Gill to deliver some of our projects. Gill will begin by working on the project to Improve Lung Utilisation and will also be involved in a number of sub-projects such as the Lung Donor Scoring System and lab work using newly established QUOD Samples to assess a link between biomarkers and the lung donor score.

Katie Morley unfortunately relinquished her role with the Clinical Audit Group after a short period to enable her to concentrate on her role covering maternity leave for the Lead Nurse Recipient Co-ordinator. The group successfully elected Ruth Sutcliffe, Cardiothoracic Transplant Co-Ordinator from Wythenshawe Hospital as our new Allied Health Professional.

In December 2019, two of the positions with the Cardiothoracic Clinical Audit Group are due for renewal. The tenure for the Mechanical Circulator Systems Representative comes to an end in December and will be open for expressions of interest following the CTAG Heart and Lung Autumn Meetings. The current incumbent Dr Steve Shaw (Wythenshawe) is welcome to stand for re-election.

The role of Paediatric Representative is currently held by Dr Zdenka Reinhardt (Freeman). By prior long-standing agreement between the two paediatric units, Dr Matthew Fenton (Great Ormond Street) will take over in this role from December 2019

The Clinical Audit Group holds four meetings each year. At the last meeting, the group unanimously decided that moving forward, we would hold three Telecons and one Face to Face meeting each year. Dates will be advised to members in due course. Additional telecons will be arranged when necessary. Membership and attendance at CTCAG will be reported annually at CTAGH and CTAGL and is listed in **Appendix A**

CLINICAL AUDIT FELLOWS

Gill Hardman commenced her position as Cardiothoracic Clinical Audit Fellow in August and we look forward to updating CTAG on her achievements in the next report. Gill has previous transplant experience from Papworth and Wythenshawe.

DATA APPLICATIONS

Since February 2019 the group received four new external applications for data.

CTCAG(19)09 – Alassar (Royal Papworth) – The impact of the introduction of a Super-Urgent Heart Allocation Scheme on outcomes of heart transplantation in the UK

CTCAG(19)10 – Alassar (Royal Papworth) – The impact of the introduction of a Super-Urgent and Urgent Lung Allocation Scheme on the outcomes of lung transplantation in the UK

The two data applications above were received from the Royal Papworth Cardiothoracic Fellow supported by Steven Tsui. SR and MAA have been working on a review of the impact of SULAS on lung transplantation outcomes, G MacGowan and SR have been working on the impact the SUHAS on the outcomes of heart transplantation outcomes. Both papers will be published once completed. The group unanimously supported the decision to decline these applications based on the duplication of work.
Application received 26/06/19 – Declined 15/08/19 (36 working days)

CTCAG(19)11 – Clements (Southampton University) – Imputation Methods with Applications to Organ Transplants.

The group agreed that the dataset could be released, NHSBT CTCAG would expect to be consulted on any papers produced from this dataset prior to any publication.
Application received 23/07/19 – Approved (with conditions) 15/08/19 (17 working days)

CTCAG(19)12 – Mehta (Wythenshawe) – Assess the outcomes of DCD lung donation in UK over the last decade, impact on lung transplantation and outcomes
Application received 08/08/19 – Approved (with conditions) 15/08/19 (5 working days)

NHSBT ORGAN SPECIFIC REPORTS

The NHSBT Annual Cardiothoracic Organ Specific Report 2018/2019 can be found on the ODT Clinical Website: Cardiothoracic Annual Activity Report 2018/2019.

CHAIRMAN'S PERSPECTIVE

The Clinical Audit Group is in its 8th year in its present format. The group involves representatives from all clinical areas of cardiothoracic transplantation and will continue in to maintain its dynamism when opportunities for elections arise, along with a natural turn-over of representatives. New members have helped generate new ideas and project proposals. Regular reports to CTAG have increased the transparency of the CAG's activities and we have new projects in development.

We are an advisory group with no staff or budget, and our work depends on the goodwill of the group's members and colleagues. We are grateful for the expertise and support of the NHSBT statistics team. Clinical Audit Group members and the statistics team have many other demands on their time; which sometimes means that worthwhile projects take longer than we would like to reach a conclusion. A number of our ongoing projects have now reached completion and work is progressing well on other projects.

One continuing frustration has been the ongoing difficulty in modifying and updating the databases on which our Audit and Research work depends. An annual VAD meeting has been set up between the Chair of CTCAG, NHS England (NHSE) and NHSBT to discuss Audit priorities and plan for the years Annual Reports; NHSE agree that they have an important role in ensuring that adequate resources are made available to maintain and update the Transplant Databases, managing the process through their contract 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. It also serves as an excellent forum to discuss scientific projects in cardiothoracic transplantation.

UPDATING THE MECHANICAL CIRCULATORY SUPPORT (LVAD) DATABASE

A further issue is 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 changes in clinical practice. 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. An MCS meeting has been set up for 19th September, hosted by NHSE, between the Chair of CTCAG, NHSE and NHSBT to discuss Audit priorities for the years Annual Reports.

UPDATE ON RISK STRATIFICATION MODEL AFTER CARDIOTHORACIC TRANSPLANTATION (matter allocated from CTAG meeting in response to Dr Sern LIM):

Risk adjustment survival after Heart Transplantation

Unadjusted and risk-adjusted survival after first adult DBD heart transplant is presented in the annual NHS BT report on cardiothoracic organ transplantation. Risk-adjusted survival is an estimate of the survival rate at a centre if they had the same mix of patients as seen nationally.

Four centres (Papworth, Newcastle, Manchester, Birmingham) have less than 1.5% difference between unadjusted and risk-adjusted survival at 30 days, 90 days and 1 year. Glasgow's unadjusted survival is

5-6% higher than risk-adjusted survival at each time point. Harefield's unadjusted survival is 6-10% lower than their risk-adjusted survival at each time point.

Table 6.1 30 day patient survival rates after first adult DBD heart transplant, by centre, 1 April 2014 to 31 March 2018

Centre	Number of transplants	% 30 day survival (95% CI) Unadjusted		Risk-adjusted	
Birmingham	102	89.2	(81.4 - 93.9)	88.7	(79.6 - 93.7)
Glasgow	45	86.7	(72.7 - 93.8)	78.5	(52.2 - 90.3)
Harefield	96	83.3	(74.2 - 89.4)	88.4	(81.1 - 92.9)
Manchester	97	94.8	(88.1 - 97.8)	93.9	(85.4 - 97.5)
Newcastle	85	89.4	(80.6 - 94.3)	89.1	(79.1 - 94.3)
Papworth	141	94.3	(89.0 - 97.1)	94.2	(88.4 - 97.1)
UK	**566**	**90.3**	**(87.5 - 92.5)**		

Centre has reached the lower 99.8% confidence limit
Centre has reached the lower 95% confidence limit
Centre has reached the upper 95% confidence limit
Centre has reached the upper 99.8% confidence limit

Table 6.2 90 day patient survival after first adult DBD heart transplant, by centre, 1 April 2014 and 31 March 2018

Centre	Number of transplants	% 90 day survival (95% CI) Unadjusted		Risk-adjusted	
Birmingham	102	85.3	(76.8 - 90.9)	84.3	(74.0 - 90.6)
Glasgow	45	84.4	(70.1 - 92.3)	78.4	(54.7 - 89.7)
Harefield	96	76.0	(66.2 - 83.4)	84.3	(76.4 - 89.6)
Manchester	97	91.8	(84.2 - 95.8)	90.6	(81.1 - 95.3)
Newcastle	85	85.9	(76.5 - 91.7)	85.1	(73.7 - 91.5)
Papworth	141	92.2	(86.4 - 95.6)	91.3	(84.2 - 95.2)
UK	**566**	**86.6**	**(83.5 - 89.1)**		

Centre has reached the lower 99.8% confidence limit
Centre has reached the lower 95% confidence limit
Centre has reached the upper 95% confidence limit
Centre has reached the upper 99.8% confidence limit

Table 6.3 1 year patient survival rates after first adult DBD heart transplant, by centre, 1 April 2014 to 31 March 2018

Centre	Number of transplants	% 1 year survival (95% CI) Unadjusted		Risk-adjusted	
Birmingham	102	81.3	(72.3 - 87.6)	79.9	(68.5 - 87.2)
Glasgow	45	81.8	(66.8 - 90.5)	74.4	(48.8 - 87.2)
Harefield	96	70.7	(60.4 - 78.7)	80.1	(71.2 - 86.3)
Manchester	97	86.5	(77.9 - 91.9)	85.0	(74.1 - 91.3)
Newcastle	85	81.2	(71.1 – 88.0)	79.8	(67.0 - 87.6)
Papworth	141	89.3	(82.9 - 93.4)	88.4	(80.7 - 93.0)
UK	**566**	**82.4**	**(79.0 - 85.3)**		

Centre has reached the lower 99.8% confidence limit
Centre has reached the lower 95% confidence limit
Centre has reached the upper 95% confidence limit
Centre has reached the upper 99.8% confidence limit

Table 6.4 5 year patient survival rates after first adult DBD heart transplant, by centre 1 April 2010 to 31 March 2014

Centre	Number of transplants	% 5 year survival (95% CI) Unadjusted		Risk-adjusted	
Birmingham	79	71.1	(59.3 – 80.0)	74.9	(61.8 - 83.4)
Glasgow	47	62.8	(46.9 - 75.2)	60.5	(36.5 - 75.5)
Harefield	65	73.7	(61.1 - 82.7)	65.8	(45.0 - 78.7)
Manchester	82	59.6	(48.1 - 69.3)	61.1	(45.3 - 72.4)
Newcastle	82	65.6	(54.2 - 74.8)	66.9	(52.0 - 77.1)
Papworth	119	79.8	(71.4 – 86.0)	79.3	(69.1 - 86.1)
UK	**474**	**69.7**	**(65.3 - 73.7)**		

Centre has reached the lower 99.8% confidence limit
Centre has reached the lower 95% confidence limit
Centre has reached the upper 95% confidence limit
Centre has reached the upper 99.8% confidence limit

Risk Adjusted Survival

The current risk adjustment model was developed by the clinical audit group in 2015. Data was obtained on 1,100 first adult isolated heart transplants performed between 1st January 2003 and 31st December 2013. Cox proportional hazard regression models were built for 30 day, 1 year and 5 year survival. Candidate variables were those chosen by the clinical audit group and those previously found to be significant in earlier risk adjustment models. Variables which reached statistical significance at the 10% level were included in the final models. Multiple imputation was used for missing values.

Adjustments were made based on feedback from the audit group and evidence of non-linear effects for some terms (spline terms were introduced). Further adjustments were made in 2016 when an interaction term between ischaemic time and the use of machine perfusion devices was introduced.

Details of the risk adjustment model are reproduced below from CTAG 16 H (11).

Table 1: Heart model results						
	30-day model		1-year model		5-year model	
Factor	p-value	Hazard ratio (95%)	p-value	Hazard ratio (95%)	p-value	Hazard ratio (95%)
Donor factors						
Cause of death	0.01		0.04		0.31	
Vascular		1		1		1
Trauma		0.97 (0.54,1.74)		1.22 (0.79, 1.89)		1.16 (0.81, 1.66)
Hypoxic		0.74 (0.35, 1.59)		0.91 (0.50, 1.65)		0.89 (0.55, 1.45)
Other		0.16 (0.04, 0.64)		0.47 (0.25, 0.91)		0.72 (0.46, 1.13)
Donor BMI (linear)	0.25	1.03 (0.98, 1.07)	0.03	1.04 (1.00, 1.07)	0.01	1.04 (1.01, 1.07)
Donor age (linear)	0.13	1.01 (1.00, 1.03)	0.01	1.02 (1.01, 1.03)	0.003	1.02 (1.01, 1.03)
Respiratory arrest	0.23		0.37		0.06	
No		1		1		1
Yes		1.40 (0.81, 2.43)		1.22 (0.79, 1.86)		1.39 (0.99, 1.94)
Recipient factors						
Recipient BMI (linear)	0.06	1.05 (1.00, 1.10)	0.71	1.01 (0.97, 1.05)	0.60	1.01 (0.98, 1.04)
Creatinine at transplant (non-linear)	0.91	Non-linear (non-sig)	0.74	Non-linear (non-sig)	0.03	**Figure 4**
VAD at transplant	0.02		0.06		0.26	
Short-term		No ECMO: 1		1.5 (0.51, 4.42)		0.63 (0.26, 1.54)
Long-term		ECMO: 4.29 (1.49, 12.36)		1		1
ECMO				4.63 (1.66, 12.89)		1.86 (0.76, 4.58)
None				1.55 (0.83, 2.90)		0.84 (0.56, 1.26)
Hospital status at transplant	0.08		0.47		0.68	
Hospital		0.69 (0.46, 1.05)		0.89 (0.65, 1.22)		1.06 (0.82, 1.37)
Not in hospital		1		1		1
Primary disease	0.05		0.42		0.27	
Dilated cardiomyopathy		1		1		1
Coronary heart disease		1.21 (0.71, 2.04)		1.26 (0.87, 1.84)		1.23 (0.90, 1.68)
Congenital heart disease		1.98 (0.93, 4.20)		1.34 (0.71, 2.51)		1.15 (0.65, 2.02)
Other		1.86 (1.16, 2.99)		1.30 (0.89, 1.90)		1.34 (0.98, 1.84)
Transplant factors						
Sex mismatch	0.24		0.03		0.30	
RM : DM		1		1		1
RM : DF		1.15 (0.65, 2.05)		1.08 (0.7, 1.66)		1.07 (0.75, 1.53)
RF : DM		1.89 (1.05, 3.40)		2.06 (1.33, 3.20)		1.48 (1.00, 2.19)
RF : DF		1.01 (0.58, 1.76)		1.11 (0.73, 1.69)		1.02 (0.72, 1.44)

Risk-adjusted survival estimates are obtained through indirect standardisation. The probability of survival for each patient is determined based on their individual risk factor values. The sum of these probabilities for all patients at a centre gives the number, E, of patients or grafts expected to survive at least one year or five years after transplant at that centre. The number of patients who actually survive the given time period is given by O. The risk-adjusted estimate is then calculated by multiplying the ratio O/E by the overall unadjusted survival rate across all centres.

Issues with current risk adjustment model

1. Out of date. CTAG 16 H (11) stated that models are reviewed and updated every three years, as a minimum, to ensure they reflect current practice. The current model will be five years old in 2020.

2. Sex-mismatching may be incorrect. The current risk adjustment model suggests that RF:DM is associated with higher risk. However, numerous publications from other registries report that the opposite sex-mismatch RM:DF is associated with higher risk. Recent analysis using predicted heart mass equations suggests that this association is due to under-sizing.

3. Uncertainty about discrimination and calibration. No summary statistics presented in CTAG 16 H (11).

4. No external validation. No process of external validation described in CTAG 16 H (11). In addition, one could argue that risk adjustment may not encourage responsible selection of recipients and donors. It is clear that recipient risk will influence post-transplant survival. Recipients at highest jeopardy such as those on short-term MCS may derive the greatest absolute gain from transplantation. However, it is also important for centres to derive an acceptable number of quality-adjusted life-years from organs that are offered for transplantation. An undesirable outcome of risk adjustment is that it could conceal the reduced survival associated with selecting high risk recipients or donor organs that may be 'higher risk' as a result of long anticipated ischaemic times.

Other risk adjustment models

Singh risk model for in hospital mortality after heart transplantation was developed from the Organ Procurement and Transplantation Network (OPTN) database.{Singh:2012fs} Data was obtained for first heart transplants between January 2007 and July 2009. The risk model was derived using multi-variable logistic regression. Models were created with recipient factors alone and with both recipient and donor factors. The recipient and donor factor model had excellent discrimination (C statistic 0.742) and calibration (Homser Lemeshow P=0.70) in the derivation cohort. It was externally validated using the

OPTN database for first heart transplants between July 2009 and October 2010. It maintained reasonable discrimination (C statistic 0.695) and calibration (Homser Lemeshow P=0.42).

Table 3. Risk Prediction Model of Posttransplant In-Hospital Mortality Using Recipient and Donor Variables

Variable	Coefficient	OR	95% CI	*P*
Age at transplant				0.002
18–64 y	...	1.00	...	
≥65 y	0.6091	1.84	(1.26–2.68)	
Diagnosis				0.002
Dilated/valvular CM	...	1.00	...	
Ischemic CM/other	0.3571	1.43	(1.04–1.96)	
Hypertrophic/ restrictive CM	0.7139	2.04	(1.04–4.01)	
Congenital heart disease	1.3968	4.04	(1.86–8.79)	
Mechanical support				<0.001
ECMO	1.6930	5.44	(1.87–15.8)	
Total artificial heart/BIVAD	1.4079	4.09	(2.56–6.52)	
LVAD	0.7208	2.06	(1.44–2.94)	
None	...	1.00	...	
Ventilator	1.2825	3.61	(2.02–6.44)	<0.001
GFR				<0.001
≥60 mL/min per 1.73 m^2	...	1.00	...	
30–59 mL/min per 1.73 m^2	0.5174	1.68	(1.22–2.31)	
<30 mL/min per 1.73 m^2	0.7943	2.21	(1.17–4.18)	
Dialysis	1.3332	3.79	(2.01–7.17)	
Total serum bilirubin				0.001
<1.0 mg/dL	...	1.00	...	
1.0–2.5 mg/dL	0.2783	1.32	(0.96–1.83)	
>2.5	0.8905	2.44	(1.55–3.82)	
Donor age				0.006
<40 y	...	1.00	...	
40–54 y	0.4221	1.53	(1.10–2.11)	
≥55 y	0.8176	2.27	(1.20–4.27)	
Ischemic time				<0.001
<4.5 h	...	1.00	...	
≥4.5 h	0.6477	1.91	(1.34–2.72)	

IMPACT risk model for one-year mortality after heart transplantation was developed from the UNOS registry.{Weiss:2011jv} Data was obtained for first heart transplants between January 1997 and December 2008. The risk model was derived using multi-variable logistic regression in a random sample of 80% of the study population. This score is based solely on recipient factors and did not include donor or institutional factors. The model had reasonable discrimination (C index 0.65) and calibration (Homser Lemeshow P=0.73) in the derivation cohort. It was externally validated using the remaining 20% of the study population but summary statistics for discrimination and calibration were not presented.

Table 2. Univariate and Multivariable Logistic Regression Used to Generate Recipient Risk Score

Covariates[a]	Univariate Analysis OR (95% CI)	*p* Value	Multivariable Analysis OR (95% CI)	*p* Value[b]	Points Assigned
Age greater than 60	1.29 (1.18–1.43)	<0.001	1.35 (1.21–1.50)	<0.001	3
Bilirubin (serum)					
0–0.99	Reference		Reference		
1–1.99	1.30 (1.17–1.44)	<0.001	1.28 (1.14–1.43)	<0.001	1
2–3.99	1.70 (1.46–1.98)	<0.001	1.49 (1.27–1.75)	<0.001	3
≥4	2.12 (1.85–2.44)	<0.001	1.96 (1.68–2.29)	<0.001	4
Creatinine clearance					
>50 mL/minute	Reference		Reference		0
30–49 mL/minute	1.10 (1.00–1.22)	0.04	1.21 (1.07–1.35)	0.001	2
<30 mL/minute	2.89 (2.32–3.58)	<0.001	2.45 (1.93–3.11)	<0.001	5
Dialysis between listing and transplant	3.11 (2.46–3.94)	<0.001	1.93 (1.49–2.51)	<0.001	4
Female sex	1.18 (1.07–1.31)	0.001	1.39 (1.23–1.57)	<0.001	3
Heart failure etiology					
Ideopathic	Reference		Reference		0
Ischemic	1.26 (1.15–1.39	<0.001	1.30 (1.16–1.45)	<0.001	2
Congenital	2.57 (2.02–3.26)	<0.001	2.80 (2.15–3.65)	<0.001	5
Other	1.25 (1.06–1.47)	0.008	1.22 (1.02–1.46)	0.02	1
Infection	1.68 (1.47–1.91)	<0.001	1.33 (1.16–1.54)	<0.001	3
IABP	1.70 (1.44–2.02)	<0.001	1.26 (1.04–1.53)	0.02	3
Mechanical ventilation prior to transplant	3.69 (3.02–4.51)	<0.001	2.10 (1.66–2.67)	<0.001	5
Race					
Caucasian	Reference		Reference		
African American	1.19 (1.05–1.34)	0.005	1.36 (1.19–1.56)	<0.001	3
Hispanic	1.01 (0.84–1.21)	0.94	1.07 (0.88–1.30)	0.65	0
Other	1.08 (0.81–1.43)	0.61	0.98 (0.72–1.34)	0.90	0
Temporary circulatory support	5.42 (4.08–7.42)	<0.001	3.26 (2.35–4.53)	<0.001	7
Ventricular assist device					
Older gen pulsatile	1.34 (1.19–1.52)	<0.001	1.30 (1.14–1.50)	<0.001	3
New gen continuous (excluding HMII)	1.99 (1.07–3.69)	0.03	2.04 (1.06–3.97)	0.03	5
Heartmate II	1.07 (0.77–1.50)	0.68	1.22 (0.87–1.72)	0.25	0
Total points possible	–	–	–	–	50 points

Suggestions

1. **The risk adjustment model in the UK should be reviewed.**

2. **Bilirubin, recipient age, recipient gender, pre-transplant mechanical ventilation and pre-transplant renal replacement therapy should be considered for inclusion in UK risk adjustment model.** These variables are all included in the Singh and IMPACT risk scores. They are already routinely collected in the UK transplant registry.

3. **More detailed categorisation of mechanical circulatory support (MCS) should be considered for inclusion in UK risk adjustment model.** In the current risk adjustment model, the only MCS categories for 30-day survival are ECMO or no ECMO. For 1-year and 5-year survival, all forms of long-term MCS (including both implantable LVAD and TAH) are considered together.

4. **Predicted heart mass (PHM) should be considered for inclusion in UK risk adjustment model**. PHM is thought to be optimal metric for size-matching in heart transplantation. It is also thought to explain the association between sex-matching and outcomes. PHM is not collected in the UK heart transplant registry. However, PHM may be easily calculated from data that are collected in the registry (age, gender, weight, height).

5. **Pulmonary vascular resistance (PVR) should be considered for inclusion in UK risk adjustment model**. PVR is thought to be a key risk factor in heart transplantation. PVR is not included in the Singh or IMPACT risk models. PVR is not collected in the UK heart transplant registry. However, PVR may be calculated from variables that are collected in the registry (mean PA pressure, PCW pressure, cardiac output).

6. **Consideration should be given to more prominent use of unadjusted data in the annual report**.

Response provided by Dr Stephen Pettit, endorsed by Group chair.

UPDATE ON AUDIT PROJECTS

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

Prof. Nawwar Al-Attar
CTAG Clinical Audit Group Chair

APPENDIX A
CLINICAL AUDIT GROUP – MEMBERSHIP AND ATTENDANCE

CTCAG Attendance	Position in CTCAG	Centre	TELECON: 21/02/19	TELECON 15/08/19	Attendance at last 4 CTCAG Meetings	% meetings attended	# meetings included to date this year
Prof. Nawwar Al-Attar	CTAG Clinical Audit Group Chair	Golden Jubilee National Hospital, Glasgow	Yes	Yes	2	100%	2
Mr Marius Berman	Donor Management and Organ Retrieval Representative	Royal Papworth Hospital, Cambridge	No	No	0	0%	2
Mrs Margaret Harrison	CTAG Lay Member Representative	CTAG Lay Member	Yes	Yes	2	100%	2
Dr Stephen Pettit	Heart Transplantation Representative	Royal Papworth Hospital, Cambridge	No	Yes	1	50%	2
Dr Zdenka Reinhardt	Paediatrics Representative	Freeman Hospital, Newcastle	No	Yes	1	50%	2
Ms Sally Rushton	Senior Statistician	NHSBT	Yes	Yes	2	100%	2
Dr Steven Shaw	Mechanical Circulatory Support Representative	Wythenshawe Hospital, Manchester	Yes	No	1	50%	2
Dr Mo Al- Aloul	Lung Transplantation Representative	Wythenshawe Hospital, Manchester	Yes	Yes	2	100%	2
Nurse Ruth Sutcliffe	Allied Health Professional	Wythenshawe Hospital, Manchester	N/A	Yes	1	50%	2
Ms Gill Hardman	CTAG Clinical Audit Fellow	Freeman Hospital, Newcastle	N/A	Yes	1	50%	2
Miss Lucy Newman	Secretary	NHSBT	Yes	Yes	2	100%	2
Attendees per meeting			6	9			

APPENDIX B
CLINICAL AUDIT GROUP – PROJECT REPORTS AND PROPOSALS

ACTIVE AND PLANNED PROJECTS

1. MCS - HM3 (L)VAD Project (Submitted to JHLT 25/07/19)
The MCS – HM3 (L)VAD Project which included data from all UK Cardiothoracic transplant Centres was submitted by Steve Shaw to JHLT – peer reviews pending.

2. HGS Study Protocol
The HGS Study Protocol has been submitted to the (?NIHR?) clinical trial website. It is now a recognised and registered trial and its hopes that it will start recruiting patients imminently.

3. Ongoing Lung Allocation Policy Work
Ongoing Lung Allocation Policy Work falls within the remit of the S/ULAS Audit Work.

4. S/ULAS Audit Work
Since MAA started leading on this work the group had one telecon at which it was decided there would be no immediate change to the process at this stage. SR and MAA defined the study timescale points as starting 20 months before and 20 months after the S/ULAS changes. The study will use outcome measures such as length of ITU stay, length of hospital stay. If SR can provide patient data, centres will confirm the lengths of stay for patients which is not currently tracked. SR and MAA will meet again in September to review patient demographics and outcomes. MAA is working with the National CF Trust who are preparing to release data from the National CF Registry to NHSBT which would enable NHSBT to identify any patient connection for Super-Urgent or Urgent listing.

5. Paediatric Focus – Re-Transplantation of Cardiothoracic Organs
The Paediatric Focus data application was submitted by ZR earlier today. SR provided preliminary data which will be adjusted to include adult data. ZR has statistical support within her centre NAA and SP would like to be involved in the project; ZR will circulate the data application to them for further input and the final version of the data application will be submitted in due course.

6. QUOD Retrieval Project Proposal
No update available to this project

7. SUHAS Publication
SUHAS Publication falls under the work being carried out on organs within CTAG, Guy MacGowan is involved as part of the Heart Allocation Sub-Group reviewing the impact of the new Heart Allocation Tiers on patients waiting for transplants. Data from two years prior and two years post introduction will be reviewed and will provide a valuable piece of audit work once completed.

8. Age related outcomes in heart and lung transplantation
MB asked the Statistics and Clinical Studies Team to look at initial analysis for this project, they agreed to take this on as ongoing project, working closely with Jason Ali at Royal Papworth. FS will be working on this and will produce an abstract for ISHLT to submit in October.

PROJECTS CURRENTLY ON HOLD

1. UK DCD Experience
No update at this stage

COMPLETED PROJECTS/PROJECTS WHERE NO FURTHER STATISTICAL ANALYSIS IS PLANNED

1. (A)CHD Project (Submitted to Heart)
No further update at this stage

2. Time After Brain Stem Death; The Effect on the Lung (Submitted to JHLT)
No further updates at this stage

3. Lung Ischemia Time Project (Submitted to AJHT)
Further work was required as a result of feedback on the Lung Ischemia Time Project. RH has requested clarity on requirements but has received no response to date

ALLIED HEALTH PROFESSIONAL PROPOSED PROJECTS

1 – Tissue Type/Sensitisation Project
Not all centres have standard sensitisation score, with some centres appearing to penalise on sensitivity. The project would focus on those centres who don't penalise sensitivity, comparing the survival outcomes for transplanted patients who are sensitised with those who are not. The NtN forms don't specify whether the patient is antibody positive or negative, this information would need to be captured directly from each centre.

2 – Sequential Offering Project
Transplant/Recipient Coordinators could receive numerous organ offers within the 45 minute timeframe given for them to respond to one offer. Does this affect the number of offers accepted at a centre? Are more organs declined when a centre is deciding on the first organ offered? Are centres losing out on organs due to logistics and are patients missing transplant opportunities, for example, over logistical issues.

Sensitisation is under review by CTAG, the Sequential Offering Project would therefore be more relevant for consideration.