NHS BLOOD AND TRANSPLANT

CARDIOTHORACIC ADVISORY GROUP

PHASE 2 – SCOUT PILOT PROJECT

Summary
Review of the data from the first 3 months of the Scout Project Phase II suggests a correlation between the attendance of a Scout and successful heart donation. However, investigation in to the underlying characteristics of donors in the scouted group and the non-scouted group is required. More data are therefore needed and further analysis required in order to ensure an effective evidence base to put to Commissioners regarding embedding the Scout role on a permanent basis.

Background
The second phase of the Scout Project was launched on 1 April 2015 and aims to:

- determine whether a Scout service can be established and adhere to attendance requirements.
- test the main hypothesis that scout attendance leads to a higher proportion of hearts retrieved and transplanted, in comparison to cardiac donors who are managed without direct CT retrieval input.
- identify *how* the presence of a scout impacts on number of hearts retrieved and transplanted.
- evaluate if Scout attendance affects retrieval and transplantability of lungs and abdominal organs.
- provide an evidence base for who is best placed to undertake cardiac donor optimisation.

Progress
Issues raised: The issues regarding forms either not being returned, or filled in incorrectly are ongoing (Table 1, Annex A). Scout Champions are being offered additional support in data collection/ submission following the appointment of a dedicated Clinical Fellow.

Data analysis: The data for the first 3 months of the project are provided at Annex A. Data from the first three months of the project suggest that presence of a Scout is associated with a 53% heart donation rate (37.5%, 68.5% CI) as opposed to a 22% heart donation rate in non-scouted patients (8.5%, 35.5% CI) although the 95% confidence intervals (CI) are wide. Moreover, it is thought that there are differences in donor characteristics between the two groups. Specifically, there may be a degree of selectiveness as to which group a donor falls in; for example, those donors that were not potential heart donors and those donors that have already been declined by all centres may not have been attended by scouts. There are also cases where scouts have chosen to attend only when the heart has been accepted. This immediately biases the analysis and hence these cases need to be excluded and further data collected.

Issues

The Steering Group has identified the following issues:

Issue	Management
Feedback that some of the Scouts attending donors do not have the competencies as outlined in the protocol – particularly in relation to completing Transoesophageal Echocardiograms (TOEs). This may be impacting on donor outcomes.	Analysis will be done to look at whether there is variation in outcomes regarding participating teams. This would help to determine whether the skill sets on teams have an impact on outcomes.
Scouting process may be extending the retrieval process and thereby impacting on donating hospital resources.	Analysis of data to examine whether there is a difference in the retrieval process between scouted CT and non-scouted CT donors. Look at time of authorisation, time of retrieval team arrival and time of knife to skin.
Birmingham had formally withdrawn from the project due to resource constraints. There was a risk that other teams may also withdraw. This would severely impact on the continuation of the project and therefore the evidence for a business case for Commissioners to support embedding the Scout role.	§ Continue with the project as planned in the short-term and explore the potential impact should any further teams cease participation. § Meet with the Scout Champions to review data from the first 3 months and agree next steps.

Conclusion

The CTAG is asked to note the progress with the Scout project and in particular note There will be a meeting to discuss progress made with the project and determine next steps in December. Scout champions in all regions and/ or representatives from each CT retrieval team will be invited to attend.

Claire Williment
Project Manager – Scout Project Phase II
September 2015

STATISTICAL ANALYSIS – RESULTS TO-DATE

SCOUT ATTENDANCE CRITERIA

1. The criteria for scout attendance are as follows;
    a. UK DBD donors
    b. Aged between 16 years and <65 years
    c. Consent for heart donation given
    d. No absolute contraindications for cardiac donation
    e. No previous history of MI or IHD
    f. Attendance would not require air travel (Unless the NORS team and Scout travel together).
    g. The NORS team is not already out on a different retrieval.
    h. The donor is within the NORS team's zone.
    i. Donor is not in Harefield's retrieval zone

2. The summaries in the sections below are based on donors that fulfil the following criteria. We have tried to match the scout attendance criteria as closely as possible but are limited in terms of the data we collect;
    a. UK DBD donors
    b. Aged between 16 years and <65 years
    c. Consent for heart donation
    d. Donor donated at least one solid organ
    e. No history of cardiothoracic disease
    f. Cause of death was not MI or IHD
    g. Retrieval team is the first on call
    h. Donor is not in Northern Ireland or Republic of Ireland
    i. Donor is not in Harefield's retrieval zone

SUMMARY OF RECRUITMENT AND FORMS RECEIVED

Table 1: Summary of recruitment and forms received between 1 April and 30 June 2015

Retrieval team first on call	Number of donors in retrieval zone that meet attendance criteria		Number of scout attendances by retrieval team		Number of forms received			
					Scouted		Non-scouted	
	Phase 2	(Phase 1)	Phase 2	(Phase 1)	N	(%)	N	(%)
Birmingham	23	(14)	5	(4)	5/5	(100%)	5/18	(28%)
Manchester	20	(15)	14	(10)	11/14	(79%)	1/6	(17%)
Newcastle	7	(5)	4	(3)	4/4	(100%)	3/3	(100%)
Papworth	20	(21)	12	(14)	7/12	(58%)	3/8	(38%)
Scotland	6	(10)	5	(6)	5/5	(100%)	0/1	(0%)
Total	**76**	**(65)**	**40**	**(37)**	**32/40**	**(80%)**	**12/36**	**(33%)**

DONATION RATES

3. Donation rates for those donors that fulfilled the scout attendance criteria (paragraph 2) between 1 April and 30 June 2015 are shown below in **Table 2**. Although the 95% confidence intervals are wide, they do not overlap which suggests that donation rates in the two groups are significantly different. However, it is thought that there are differences in donor characteristics between the two groups. Specifically, there may be a degree of selectiveness as to which group a donor falls in; for example, those donors that were not potential heart donors and those donors that have already been declined by all centres may not have been attended by scouts. There are also cases where scouts have chosen to attend only when the heart has been accepted. This immediately biases the analysis and hence these cases need to be excluded and further data collected. Risk-adjustment is also required to account for any differences in the donor case mix.

Table 2: Observed donation rates (1 April 2015 to 30 June 2015)		
	Donation rate	**95% confidence interval**
Scouted donors	53%	(37.5%, 68.5%)
Non-scouted donors	22%	(8.5%, 35.5%)

TRAJECTORY OF RECRUITMENT

4. Over the first three months of the study, there have been 76 donors that fulfilled the scout attendance criteria. There has been variation between months (19 in April, 32 in May and 25 in June), but assuming an average of 25 donors per month we could expect to recruit approximately 300 donors in total over the year 1 April 2015 to 31 March 2016.

5. Before the project began, sample size calculations were run to estimate the total number of donors required in the study to reach the required power that would lead to a robust statistical conclusion.

6. These calculations are dependent on what the true donation rates are in the scouted group and non-scouted group of donors. This is illustrated in the tables below. The range of donation rates used in the calculations (30% and 35% for the non-scouted group and 34% to 52% for the scouted group) were chosen based on the observed donation rates in Phase 1 of the Scout Project. The Phase 1 donation rates were however flawed as there was bias noted in the two groups and Phase 1 excluded donors that were outside a two hour travel radius of a retrieval team. Note that these calculations also assume that approximately three quarters of the total donors fall in to the scouted group as scouts are expected to attend all donors that fulfil the attendance criteria except when the retrieval team are already committed to a retrieval.

Table 3: Sample size calculations based on 30% donation rate in non-scouted group	
Assumed donation rate in scouted group	Required total no. donors
48%	308
46%	388
44%	504
42%	676
40%	960
38%	1480
36%	2592
34%	5728

Table 4: Sample size calculations based on 35% donation rate in non-scouted group	
Assumed donation rate in scouted group	Required total no. donors
52%	356
50%	456
48%	604
46%	836
44%	1240
42%	2032
40%	3944
38%	10816
36%	95968

SUMMARY

7. Over the first three months of the project, only 53% (40/76) of donors that fulfilled the attendance criteria were attended by a scout, which is lower than assumed in the sample size calculations above. The difference between observed donation rates is also much larger than assumed above (22% in the non-scouted group versus 53% in the scouted group).

8. Due to these differences, despite only recruiting 76 donors in total, statistical significance has already been reached, suggesting a significant difference between the two groups. However, as noted in paragraph 3, it is essential that additional data are collected and the project continues in order to reach a robust conclusion.

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Statistics and Clinical Studies