

NHS BLOOD AND TRANSPLANT
RESEARCH, INNOVATION AND NOVEL TECHNOLOGIES ADVISORY GROUP
TWO MONTH REVIEW OF THE RESEARCH ALLOCATION SCHEME

SUMMARY

BACKGROUND

- 1 A new allocation scheme for research organs went live on 20 February 2017 where studies are ranked in order of priority. Previously, research organs were offered to studies on a geographical basis. A two month review was undertaken to determine the effectiveness of the offering of organs for research under the new scheme. This paper presents the results of this two month review.

DATA AND METHODS

- 2 Data collected by NHSBT on organs used for research is limited and does not capture the full offering details. An ad-hoc spreadsheet for the purpose of this analysis was therefore created to collect such information. The Duty Office completed this spreadsheet by going through their log notes for all donors where an organ was retrieved but not transplanted within a two month period from 20 February 2017 to 20 April 2017.

SUMMARY

- 3 Over the duration of the two month review from 20 February to 20 April 2017, 133 organs were retrieved for transplantation but were not transplanted. 12 (9%) did not have consent for research and so the potential to be used for research was lost. 7 (5%) were not offered for research for other reasons such as; 'the organ was kept for histology', 'lab started isolating but it was not digesting' and 'pancreas disintegrated'.
- 4 Of the 121 organs which had research consent, 114 (94%) were offered for research; 78 (68%) of these were accepted/used for research and 36 (32%) were discarded. Where the organ was discarded, two thirds of studies did not respond to an offer and the other third responded to decline the offer. Where there was no response to an offer, 21 (88%) offers were outside of the 9am to 5pm weekday timeframe. Reasons studies gave for decline were mainly due to staff unavailability, anatomy, poor organ quality and geographical location.
- 5 Five studies were unable to use organs due to geographical issues. Limited travel time information illustrated that the median time between the organ location (for cases where the organ was located at a retrieval centre only) and the final study location was 1 hour 47 minutes for these cases.
- 6 The median time from the start of the last offer for transplantation to the time the research organ was offered was 62 minutes (IQR: 46 – 452 minutes). This time includes the time to decline of the offer of an organ for transplantation which could be up to 45-60 minutes.

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TWO MONTH REVIEW OF THE RESEARCH ALLOCATION SCHEME

BACKGROUND

- 1 Until recently, research organs were offered to studies on a geographical basis via a phone call. A new allocation scheme for research organs was introduced on 20 February 2017. Research studies are now ranked through a scoring system such that studies with capabilities of improving an organ for the purposes of transplantation are given higher priority.
- 2 Research organs are now offered to studies via text messages. The organ is allocated to the highest ranked study that responds to an offer within 45 minutes. Organs which are already located at the highest ranked study or livers which are used for hepatocytes are not offered through the ranking system. Pancreas islets are also permitted to be kept by the isolating lab.
- 3 A two month review was undertaken to determine the effectiveness of the offering of organs for research under the new scheme. This paper presents the results of this two month review.

DATA AND METHODS

- 4 Data collected by NHSBT for research organs is limited. A spreadsheet was therefore created for the purpose of this analysis to collect fuller information including; the time of offer, reasons for not offering an organ for research, the organ location at the time of offer, studies that responded to an offer and whether they responded within 45 minutes. The Duty Office completed the spreadsheet by going through their log notes for all donors where an organ was retrieved but not transplanted within a two month period from 20 February to 20 April 2017.
- 5 Organs that went for research and were successfully transplanted as a result are not distinguished from other routine transplants on the transplant database and can thus not be included as research organs.
- 6 Studies provide progress reports to RINTAG which include the reasons for decline of an organ for research. The reasons listed in the paper are taken from a progress report dated June 2017.

RESULTS

- 7 A summary of organs retrieved for transplantation from 20 February to 20 April 2017 is shown in **Table 1**. No organs were identified as being retrieved solely for the purposes of research. 133 (16%) of the total number of organs retrieved which were not transplanted (818) and were thus potentially available to use for research.

Table 1 Summary of organs retrieved for transplantation, 20 February 2017 to 20 April 2017

Organ	Retrieved	Transplanted		Not transplanted		Offered for research ³		Used for research		Consent and disposed		No research consent	
	N	N	% Ret ¹	N	% Ret ¹	N	% not txd ²	N	% not txd ²	N	% not txd ²	N	% not txd ²
Liver	166	135	81	31	19	30	97	21	68	9	29	1	3
Liver segments	33	29	88	4	12	2	50	2	50	2	50	0	0
Kidney	434	388	89	46	11	40	87	24	52	16	35	6	13
Pancreas	60	32	53	28	47	23	82	12	43	12	43	4	14
Islets	27	4	15	23	85	18	78	18	78	4	17	1	4
Bowel	1	1	100	0	0	0	0	0	0	0	0	0	0
Heart	31	31	100	0	0	0	0	0	0	0	0	0	0
Single Lung	65	65	100	0	0	0	0	0	0	0	0	0	0
Double Lung	1	0	0	1	100	1	100	1	100	0	0	0	0
Total	818	685	84	133	16	114	86	78	59	43	32	12	9

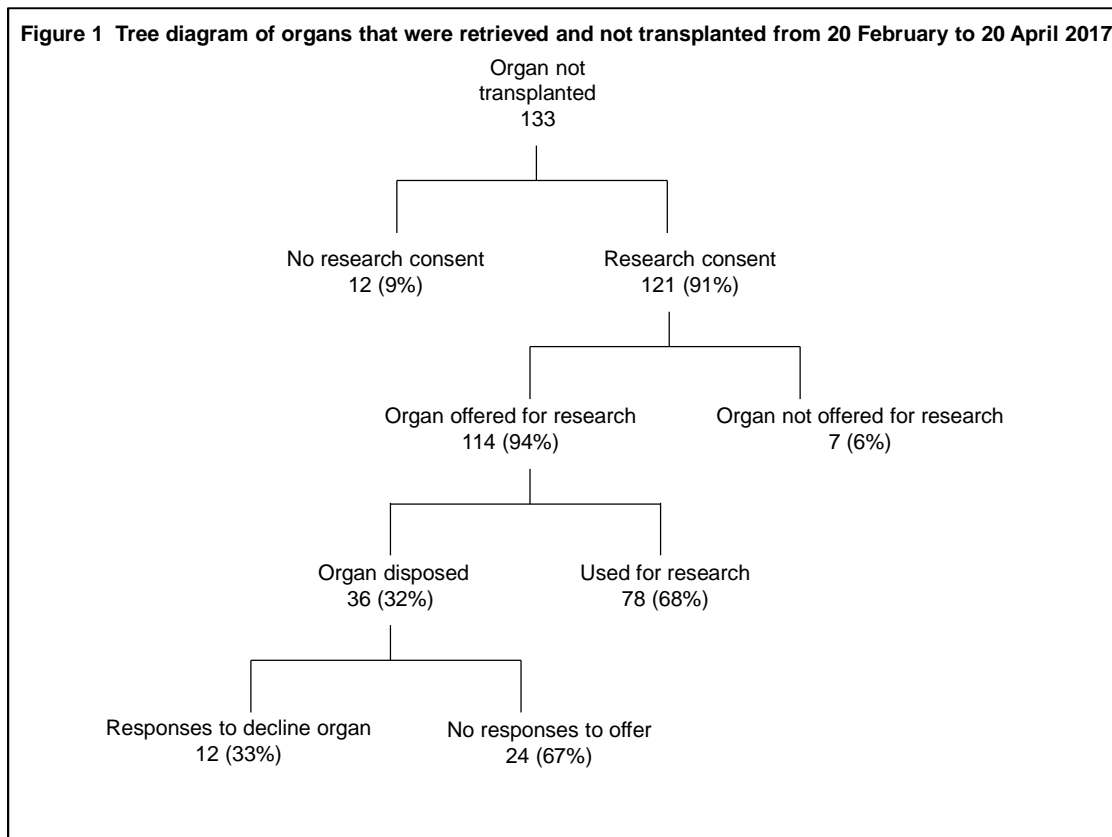
¹ Percentage of organs retrieved
² Percentage of organs not transplanted
³ Offered for research includes islets and hepatocytes that were not offered though the ranking system

- 8 Of those 133 organs that were retrieved for transplant but were not transplanted, 12 (9%) did not have consent for research. 78 (59%) were used for research but 43 (32%) were disposed of even though consent for research was given. Overall, 114 (86%) of the organs that were not transplanted were offered for research.
- 9 7 (5%) of the 133 organs that were not transplanted were not offered for research for reasons other than no research consent. Reasons for not offering an organ for research where consent had been given are shown in **Table 2**. The majority of reasons were due to the anatomy of the organ.

Table 2 Reasons for not offering an organ for research where consent was given

Reasons for not offering	N
Isolating lab allowed to keep	1
Pancreas had disintegrated and therefore unusable for research	1
Pancreas not retrieved for transplant but en-bloc liver, disposed of when liver then declined by liver and transplant	1
Right lobe and segment IV cut down and disposed of	2
Very small, the lab started the isolation but it was not digesting so disposed of	1
Whole organ kept for histology	1
Total	7

10 **Figure 1** illustrates the outcome pathway of the 133 organs which were retrieved and not transplanted from 20 February to 20 April 2017.



11 Of the 133 organs that were not transplanted, 121 (91%) gained research consent. 114 (94%) organs that gained research consent were offered. Of which 36 (32%) were disposed of; 12 (33%) studies responded to decline the organ and 24 (67%) studies did not respond. Where there was no response to an offer, 21 (88%) offers were made outside of the 9am to 5pm weekday timeframe.

12 Furthermore, **Table 3** explores the time of responses to offers for research. This shows that 81% of offers that were made in the weekday between 9am to 5pm were accepted for research compared to only 50% when the offer was made out of hours in the weekday and 62% at the weekend.

Table 3 Outcome of organs offered for research according to time of offer

Time of offer	Accepted for research		Not accepted for research	
	N	%	N	%
Weekday 9 - 5	22	81	5	19
Weekday out of hours	20	50	20	50
Weekend	18	62	11	38
Missing	18	100	0	0
Total	78	68	36	32

Please note: 22 were not offered through the ranking scheme either because they were used 1) for liver hepatocytes, 2) were pancreas islets or 3) the location of the organ was already at the highest ranked study hence why there are missing offer times.

- 13 **Table 4** states the reasons studies gave for declining an organ for research. If a study reported several reasons, the reasons have been counted separately. The main issues related to staff unavailability, anatomy and organ quality.

Table 4 Reasons for studies declining an organ for research from progress reports June 2017

Reasons for declining an organ for research	N
Staffing issues	11
Anatomy or organ quality	8
Not reported	6
Geographical location and long cold ischemia time	5
Logistics – no access to blood products	2
Lack of availability of machines	2
Didn't hear text message	2
Malfunctioning offering system	1
Logistics	1
Total	38

- 14 Another common reason for decline was that the geographical location was too far or because of an increased cold ischemia time. It was only possible to calculate the travel times from the organ location to the final study location if the organ was originally located at a retrieval centre. The median travel time for the 45 known organ locations to final study locations was 107 minutes (IQR: 33 – 136 minutes).
- 15 Long cold ischemia times may occur due to the length of the offering process. The median number of offers for transplantation prior to offering for research was 7 (IQR: 2 – 8). The median time from the start of the last offer for transplantation to the time the research organ was offered was 62 minutes (IQR: 46 – 452 minutes), 15 cases were under 50 minutes for 53 known offer times. The Duty Office state that offers for research organs are made as soon as all offers for transplantation have been declined by centres.
- 16 **Table 5** summarises the offers of organs for research made between 20 February and 20 April 2017. 14 studies responded to decline an offer and responses are acceptances and declines. The studies are ranked in order of priority as at 20 February 2017. More information on the studies can be found in the **Appendix**.
- 17 There were a total of 103 responses to 91 offers made through the ranking system. Three responses were after the 45 minute timeframe. The median number of responses per offer was 1 (IQR: 0-2); the largest number of responses to an offer was 5. Some studies did not respond to any offers. 23 liver/segments and islets used for research and not offered through the ranking system are also shown in **Table 5**.

Table 5 Responses to offers including declines and acceptances for 78, 20 February 2017 to 20 April 2017

Organ	Study Number	Rank	Location	Number of organs offered through allocation scheme	Offer responses within 45 minutes	Offer responses over 45 minutes	Total organs received through allocation scheme	Total organs received that were not offered
Liver	21	1	Cambridge	25	2	0	1	1
Liver	62	1	Birmingham	25	11	0	1	0
Liver	60	2	Oxford	25	6	0	5	0
Liver	56	3	Edinburgh	25	1	0	1	0
Liver	52	4	Newcastle	25	1	0	2 ³	0
Liver	50	5	Royal Free	25	0	0	0	0
Liver	35	6	Birmingham	25	3	0	0	0
Liver	18	7	Royal Free	25	0	0	0	0
Liver (hepatocytes)	68	7	King's	25	0	0	0	1
Liver	33	8	Birmingham	25	2	0	1	0
Liver	33/62/35	.	Birmingham	25	0	0	0	1
Liver	6	Unknown ²		25	1	0	0	0
Liver	65	NA ¹	Edinburgh	25	0	0	0	0
Liver hepatocytes	Unknown ²	NA ¹						4
Kidney	53	1	Cambridge	40	4	1	1	0
Kidney	37	2	Oxford	40	8	0	4	0
Kidney	48	2	Newcastle	40	6	0	4	0
Kidney	63	2	Guy's	40	4	0	0	0
Kidney	49	3	Birmingham	40	0	0	0	0
Kidney	2	4	Cambridge	40	5	0	3	0
Kidney	23	4	Cambridge	40	9	0	8	0
Kidney	2/23	4	Cambridge	40	0	0	2	0
Kidney	19	5	Bristol	40	1	0	0	0
Kidney	40	6	Royal Free	40	0	0	0	0
Kidney	30	7	Hammersmith	40	0	0	0	0
Kidney	31	Tissue bank ²	Cardiff	40	1	0	2	0
Pancreas	20	1	Newcastle	23	6	0	4	0
Pancreas	45	2	Oxford	23	4	0	2	3
Pancreas	3	3	Cambridge	23	0	0	0	0
Pancreas	50	3	Royal Free	23	14	0	9	0
Pancreas	34	4	Worcester	23	0	0	0	0
Pancreas	64	5	Oxford	23	7	0	4	0
Pancreas islets	40	6	Royal Free	3	1	0	0	0
Pancreas	30	7	Hammersmith	23	0	0	0	0
Pancreas islets	46	NA ¹	Edinburgh	3	3	2	1	6
Pancreas islets	47	NA ¹	King's	3	0	0	0	0
Pancreas islets	Unknown ²	NA ¹		0	0	0	0	6
Heart	67	1	Imperial	0	0	0	0	0
Lung	66	0	Newcastle	0	0	0	0	0
Lung	58	0	Edinburgh	0	0	0	0	0
Lung	38	NA ¹	Harefield	0	0	0	0	1
Lung	59	NA ¹	Belfast	0	0	0	0	0
Total				91	100	3	55	23

¹ NA: studies which are exempt from the national allocation scheme via the Duty Office

² Unknown studies

³ On one occasion no responses to offers so Newcastle kept the organ

CONCLUSION

- 18 Whilst 94% (114) of organs with consent for research were offered for research, 32% of these were organs were not subsequently used for research and were disposed of. The main reason the organs were discarded were because either the study reported that they could not use the organ or because there were no responses to those offers. In the case where there was no response, 88% of offers were outside of the 9am to 5pm weekday timeframe. Reasons studies gave for decline were mainly due to staff unavailability, anatomy, poor organ quality and geographical location.
- 19 20% of organs that were used for research were not offered through the ranking system. For organs that were offered through the ranking system, studies that were lower in the ranking were still able to receive an organ. The median number of responses per offer was 1 which gave responding studies a good chance of receiving an organ.
- 20 Five studies were unable to use organs due to geographical issues. Limited travel time information illustrated that the median time between the organ location (for cases where the organ was located at a retrieval centre only) and the final study location was 1 hour 47 minutes.
- 21 Long cold ischemia times may occur due to the length of offering process. The median time from the start of the last offer for transplantation to the time the research organ was offered was 62 minutes (IQR: 46 – 452 minutes). This time includes the time to decline of the offer of an organ for transplantation which could be up to 45-60 minutes.

Appendix

Organ	Study	Rank	Location	Study Title
Heart	67	1	Imperial	Structural and functional analysis of intact myocardium and isolated cells from explanted hearts
Lung	66	1	Newcastle	Further Evaluation of Ex Vivo Lung Perfusion to Improve Transplantation Outcomes
Lung	58	2	Edinburgh	ENLIGHTEN - Multiplexed Optical Molecular Imaging and Sensing during Ex Vivo Lung Perfusion (EVLV)
Lung	38	NA	Harefield	Ex vivo transplant platforms used to explore the pathogenesis of acute lung injury
Lung	59	NA	Belfast	Human ex-vivo lung perfusion research consortium UK (HELP RCUK)
Liver	21	1	Cambridge	Development of pre-transplant normothermic perfusion reconditioning for human livers donated after circulatory death
Liver	62	1	Birmingham	Viability testing and transplantation of marginal livers - VITTAL
Liver	60	2	Oxford	Exploring the structural and functional effects of normothermic machine perfusion and de-fating agents on human steatotic livers
Liver	56	3	Edinburgh	Human Hepatic Progenitor Cells as a Source of Liver Regeneration
Liver	52	4	Newcastle	Establishing ex-vivo normothermic and hypothermic perfusion of livers for transplantation
Liver	50	5	Royal Free	Organ regeneration and disease modelling using 3D biological scaffold
Liver	35	6	Birmingham	Normothermic Liver Perfusion Study (The development of NMLP for improvement of marginal human donor liver quality)
Liver	18	7	Royal Free	Liver Viability Enhancement during Transportation - LIVET
Liver	68	7	King's	Hepatocyte Transplantation Project: Studies on isolated hepatocytes
Liver	33	8	Birmingham	Expression and Function of Immune Regulatory Proteins in Human Liver
Liver	65	NA	Edinburgh	Development of a therapeutic 3D implantable liver organoid -scaffolding materials for liver tissue engineering
Kidney	53	1	Cambridge	Quality assessment of Human Kidneys by Ex-vivo Normothermic Perfusion prior to Transplantation
Kidney	37	2	Oxford	Normothermic Perfusion of Discarded Kidneys
Kidney	48	2	Newcastle	Establishing ex vivo normothermic perfusion (EVNP) of kidneys for transplantation
Kidney	63	2	Guys	Transplanting the untransplantable - extending antibody incompatible transplantation using a normothermic perfusion model with cytoprotective agents
Kidney	49	3	Birmingham	A study to determine the mechanism and effect of machine perfusion on cadaveric kidneys unsuitable for transplantation
Kidney	2	4	Cambridge	Study of renal ischaemia-reperfusion injury and its amelioration
Kidney	23	4	Cambridge	Characterisation of ischaemia reperfusion injury in human kidneys Non-transplantable Kidneys
Kidney	19	5	Bristol	Establishment of cultured human glomerular cells for study of glomerular function in vitro
Kidney	40	6	Royal Free	Identification of genes involved in renal, electrolyte and urinary tract disorders
Kidney	30	7	Hammersmith	Use of Machine Perfusion for Improving Allograft Viability
Pancreas islets	20	1	Newcastle	Process development for islet isolation targeted at enhancing islet yield and viability
Pancreas islets	45	2	Oxford	Studies of Factors Influencing the Structure and Function of Human Pancreatic Islets for Transplantation
Pancreas	3	3	Cambridge	Study of Pancreas Function, Physiology, Pathology and Therapeutics
Pancreas	50	3	Royal Free	Organ Regeneration and Disease Modelling Using 3D Biological Scaffold
Pancreas	34	4	Worcester	A pre-clinical study of human islet function to improve long-term graft survival
Pancreas	64	5	Oxford	Assessment and Significance of Pancreatic steatosis in pancreas transplantation and its associations with graft pancreatitis
Pancreas islets	40	6	Royal Free	Identification of genes involved in renal, electrolyte and urinary tract disorders
Pancreas	30	7	Hammersmith	Use of Machine Perfusion for Improving Allograft Viability
Pancreas islets	46	NA	Edinburgh	Edinburgh Islet Lab - supporting various islet research studies
Pancreas islets	47	NA	King's	King's Islet lab