

NHS BLOOD AND TRANSPLANT**RESEARCH, INNOVATION AND NOVEL TECHNOLOGIES ADVISORY GROUP****AVAILABILITY OF ORGANS FOR RESEARCH****SUMMARY****BACKGROUND**

- 1 This paper investigates the pathway of untransplantable organs that were offered to and received by research studies between 1 January and 31 July 2021. This includes organs that were retrieved for transplantation, deemed unsuitable and then offered for research, as well as organs that were deemed untransplantable before removal and offered through the INOAR process.

DATA AND METHODS

- 2 Untransplantable organs were obtained from the UK Transplant Registry for UK deceased donors between January 2012 and July 2021. Research outcome was split into three categories: no generic research consent, used for research (under generic or specific consent) and organ disposed of with generic research consent.
- 3 Research organ offering data was also obtained from the ODT Research Team who are copied into research offers (generic consent only). Text message offer data is manually transcribed onto a spreadsheet and combined with EOS data to determine which studies received the organs.

CONCLUSION

- 4 Overall, the total number of untransplantable organs has steadily increased over time. In addition, the proportion of these organs that have consent/authorisation for research has increased to 97% for 2021 so far.
- 5 The number of organs used for research fell in 2020 due to the coronavirus pandemic. The numbers have increased again in 2021 so far; 265 organs that were retrieved for transplantation then deemed unsuitable have been used for research and this is in line with the years prior to 2020.
- 6 The proportion of discarded organs where generic research consent/authorisation was ascertained is substantially higher than in previous years; 13% in 2015 compared to 39% for the period January to July 2021. However, the rate is lower than the previous three years.
- 7 During the period January to July 2021, 511 retrieved but untransplanted organs were offered to researchers through the National Allocation Scheme. 254 of the 511 organs offered for research were accepted by studies on the ODT Research Registry. In addition to these 254 organs, an additional 11 were used but were not offered through the NAS.
- 8 Utilised research organs were distributed across many studies which suggests that studies that were ranked lower through the allocation scheme were still able to obtain research organs.

NHS BLOOD & TRANSPLANT

RESEARCH, INNOVATION AND NOVEL TECHNOLOGIES ADVISORY GROUP

AVAILABILITY OF ORGANS FOR RESEARCH

BACKGROUND

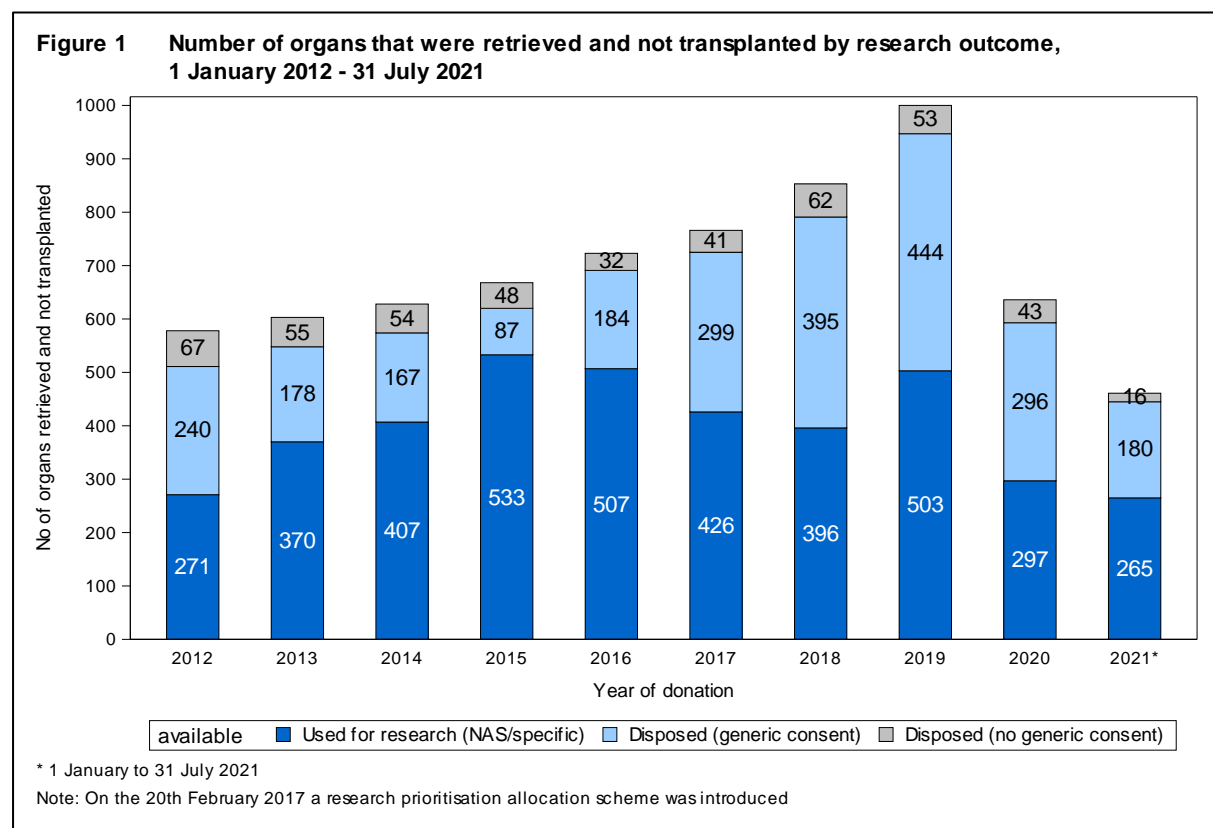
- 1 This paper investigates the pathway of organs that were untransplantable; these organs have the potential to be available for research purposes. However, such organs cannot be used for research through the National Allocation Scheme (NAS) if there is no suitable generic consent/authorisation. In some cases, these organs can be used for research if there is specific consent/authorisation.
- 2 In addition, some of these organs are discarded for a wide range of other reasons (e.g., out-of-hours, not suitable for particular trials, logistical reasons). Within this paper we assess the availability of untransplantable organs and identify the number of such organs offered to and received by each research study.

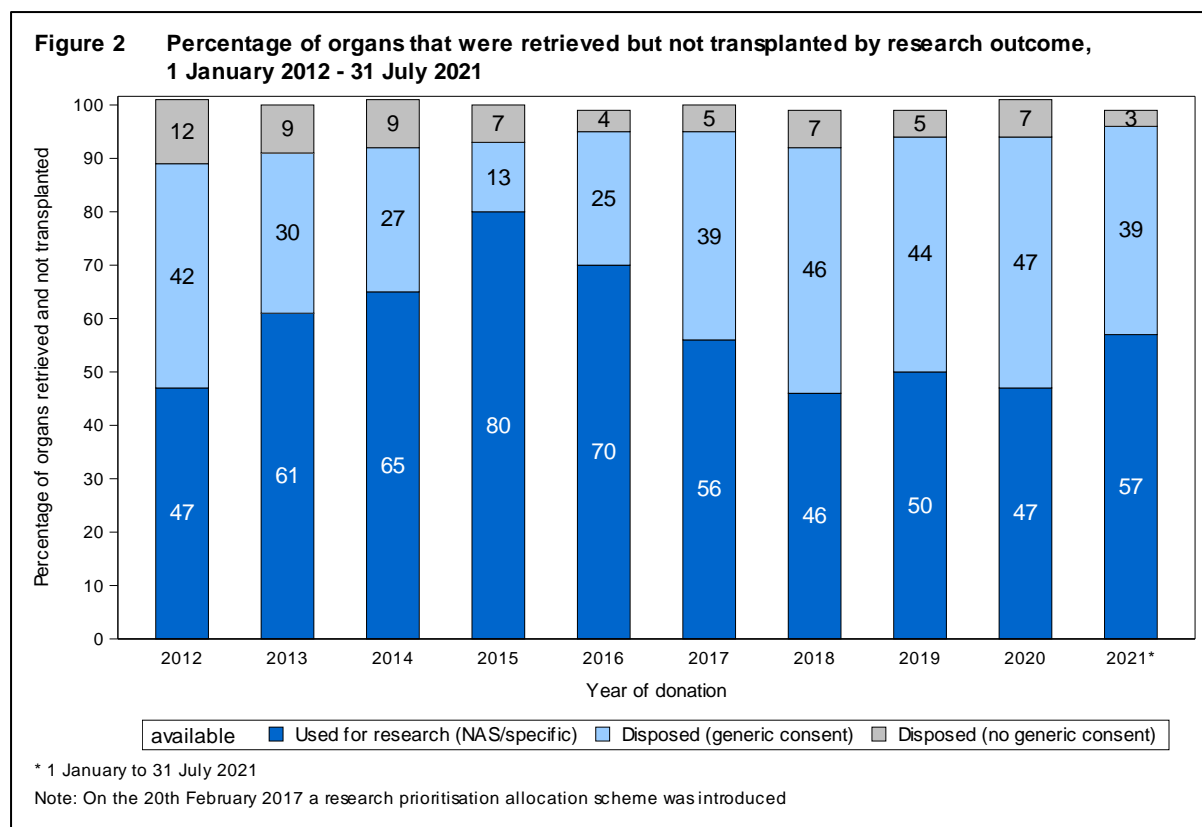
DATA AND METHODS

- 3 Organs that were untransplantable were obtained from the UK Transplant Registry for UK deceased donors between 1 January 2012 and 31 July 2021. Research outcome was split into three categories: no generic research consent, used for research (under generic or specific consent) and organ disposed of with generic research consent.
- 4 Research organ offering data was also obtained from the ODT Research Team who are copied into research offers (generic consent/authorisation only). Text message offer data is manually transcribed on to a spreadsheet and combined with EOS data to determine which studies received the organs. Please note that there may be some organs that were allocated directly to studies without an offer message being sent out, and therefore these cases will not be included in this dataset.
- 5 Organs that were offered for research in 2021 so far are presented in terms of which research studies they were offered to and which studies (if any) they went to. Details on each of these research studies which are listed in the **Appendix**. Study rankings are as of October 2021.
- 6 Livers isolated for hepatocytes (transplanted or not transplanted) have been excluded from this analysis.

RESULTS

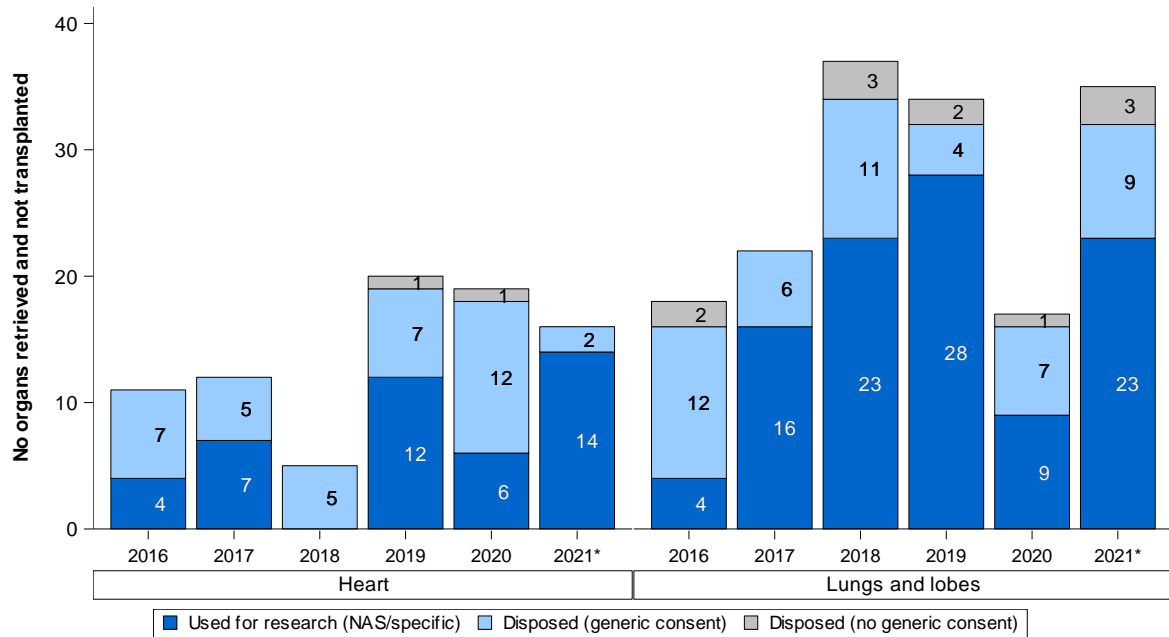
- 7 **Figure 1** shows the research outcome of UK donor organs that were untransplantable between 1 January 2012 and 31 July 2021. Overall, the total number of untransplantable organs has steadily increased since 2012. The availability of organs for research was at an all-time high in 2019. There was a decrease in the number of organs used for research in 2020 due to the coronavirus pandemic. The numbers have increased again in 2021 so far; 265 organs have been used for research and this is in line with the years prior to 2020. Please note that this paper marks the third year that ODT Research Team data have been merged with UK Transplant Registry data. Data from 2019 onwards has been modified to reconcile both sets of data. Hence the accuracy of the results may be higher from 2019 onwards than in previous years.
- 8 The proportion of untransplantable potential organs available for research are shown in **Figure 2**, by research outcome from 1 January 2012 to 31 July 2021. Consent/authorisation for research has been fairly constant in the last seven years ranging from 93% to 97% in 2021 so far and so the proportion of organs discarded due to a lack of research consent/ authorisation is relatively small.





- 9 In 2015, the number of retrieved but untransplanted organs used for research (under generic or specific consent) was at its highest at 534, after which point the number decreased each year to 400 in 2018 before increasing to 507 in 2019. In 2020, the numbers were lower due to the coronavirus pandemic and 299 organs were used for research. The number of organs used for research has increased again to 265 organs in 2021 so far.
- 10 Discard rates for organs with generic research consent/authorisation have remained fairly high in recent years, at 47% for the 2020 calendar year. However, the discard rate has fallen to 39% for 2021 so far.
- 11 The same information from **Figure 1** (number of untransplantable organs) is broken down by organ and illustrated in terms of cardiothoracic organs in **Figure 3** and abdominal organs in **Figure 4**.
- 12 The number of cardiothoracic organs available for research is small, as seen in **Figure 3**. The number of cardiothoracic organs used for research in the first seven months of 2021 is higher than the previous five full years for hearts (n=14) and also for each year except 2019 for lungs (n=23 compared with 29 in 2019).
- 13 **Figure 4** shows that until 2020, the number of abdominal organs available for research has generally been increasing, particularly for kidneys and livers. Numbers were lower for 2020 due to reduced donors and suspension of research studies due to the coronavirus pandemic but have been increasing again in 2021 so far.

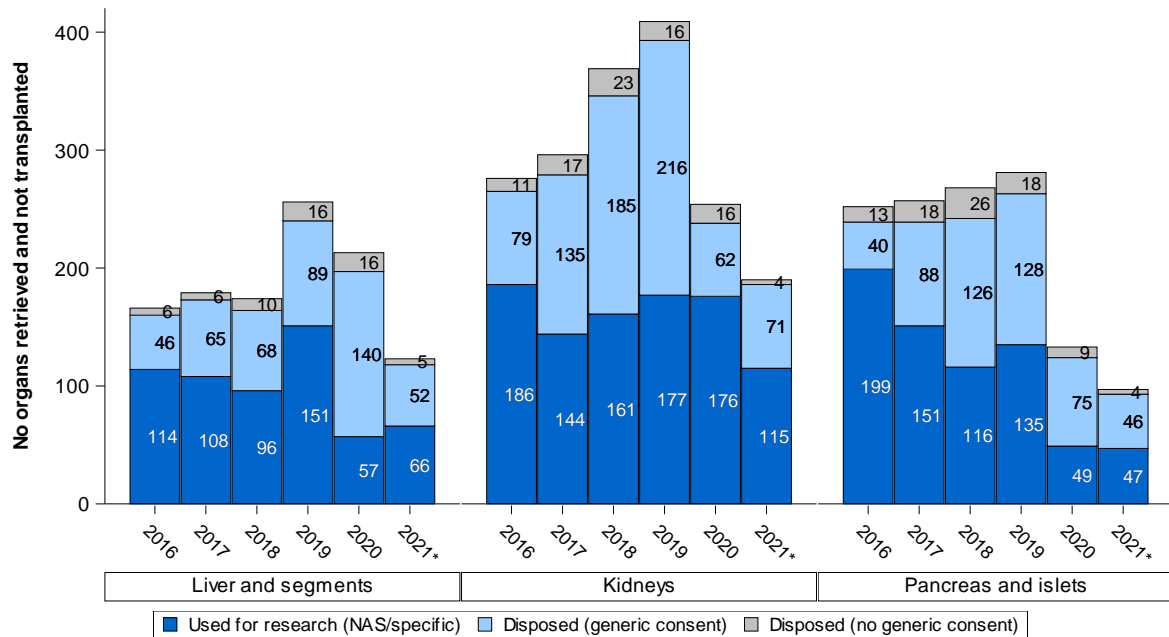
Figure 3 Number of cardiothoracic organs that were retrieved but not transplanted by research outcome and organ from 2016 to 2021



* 1 January to 31 July 2021

Note: On the 20th February 2017 a research prioritisation allocation scheme was introduced

Figure 4 Number of abdominal organs that were retrieved and not transplanted by research outcome and organ from 2016 to 2021



* 1 January to 31 July 2021

Note: On the 20th February 2017 a research prioritisation allocation scheme was introduced

14 **Table 1** shows the total number of retrieved but untransplanted organs that were offered and accepted by organ type from 1 January 2021 to 31 July 2021. 511 organs from 359 deceased organ donors were offered to researchers through the National Allocation Scheme (NAS) during this time. 254 of the 511 organs offered for research were accepted by studies on the ODT Research Registry. 152 organs were disposed, 97 organs were offered for INOAR and not retrieved and of the 8 remaining organs:

- 1 pancreas was returned to the donor's body
- 1 lung was returned to the donor's body
- 1 lung was transplanted when the recipient centre changed their mind
- 1 heart was used for valves (which should have occurred before being offered for research)
- 1 kidney was used for histopathology analysis
- 1 pancreas was used for histopathology analysis
- 1 pancreas offer went to the wrong pager group
- 1 heart went to NHSBT Tissue and Eye Services

15 In addition to these 254 organs used for research, an additional 11 were not offered through the NAS but were used for research (hence used under specific consent/authorisation). This brings the total to 265 organs that were used for research during 1 January 2021 to 31 July 2021.

16 69% of organs were offered outside of core hours or over weekends and bank holidays. 59% of organs offered during core hours were accepted, 44% offered outside of core hours were accepted and 38% of organs offered over weekends and bank holidays were accepted.

Table 1 Organs offered and accepted for research through the National Allocation Scheme (NAS) 1 January 2021 to 31 July 2021

Organ type	Organs offered	Organs accepted	
	N	N	% of offered
Heart	80	14	18
Lungs	59	23	39
Liver	113	65	58
Kidney	176	113	64
Pancreas	83	39	47
TOTAL (offered through NAS)	511	254	50
TOTAL (not offered through NAS)	511	11	-
TOTAL	511	265	-

17 **Table 2** and **3** show the total number of retrieved but untransplanted organs offered to and received by research studies from 1 January to 31 July 2021 (including those received outside of the NAS), for each of the cardiothoracic and

abdominal organs, respectively. The tables show that the research organs utilised were distributed across many studies as such lower ranked studies were still able to obtain research organs overall.

Table 2 Cardiothoracic organs received by study from 1 January to 31 July 2021

Organ	Study Number	Location	Ranking as at October 2021	Organs offered through NAS	Organs received through NAS		Organs received outside NAS	Total organs received	
				N	N	% of offered	N	N	%
Hearts	83 ¹	Newcastle	1	80	1	1	0	1	7
	90	Newcastle	2	80	7	9	0	7	50
	67 ²	Imperial	3	80	1	1	0	1	7
	118	Newcastle	4	39	5	13	0	5	36
	Total				14		0	14	100
Lungs	66	Newcastle	NA ³	59	9	15	0	9	39
	58	Edinburgh	NA ³	59	12	20	0	12	52
	101	Newcastle	3	59	2	3	0	2	9
	Total				23		0	23	100
Total cardiothoracic organs					37			37	100

NOTES

¹ Study 83 is unable to accept hearts that have already been on the Organ Care System (OCS)

² One heart received through NAS were used for both study 67 and 106 (both based at Imperial)

³ As of the May 2019 RINTAG meeting, lung studies 58 and 66 have agreed to allocate the lungs between themselves

Table 3 Abdominal organs received by study from 1 January to 31 July 2021

Organ	Study Number	Location	Ranking as at October 2021	Organs offered through NAS	Organs received through NAS		Organs received outside NAS	Total organs received	
				N	N	% of offered	N	N	%
Liver and segments	21	Addenbrookes	1	113	1	1	0	1	2
	35	Birmingham	3	113	2	2	0	2	3
	68	King's	3	113	2	2	0	2	3
	56	Edinburgh	5	113	9	8	0	9	14
	102	Oxford	6	113	2	2	0	2	3
	103	King's	6	85	10	12	0	10	15
	105	Oxford	6	76	3	4	0	3	5
	84	Birmingham	7	113	10	9	0	10	15
	86 ¹	Birmingham	7	113	26	23	0	26	39
	Unknown				0	0	1	1	2
	Total				65		1	66	100

NOTES

¹ 25 livers received through NAS were used for both study 84 and 86

Table 3 Abdominal organs received by study from 1 January to 31 July 2021 (ctd.)

Organ	Study Number	Location	Ranking as at October 2021	Organs offered through NAS	Organs received through NAS		Organs received outside NAS	Total organs received		
				N	N	% of offered	N	N	%	
Kidney	48	Newcastle	1	176	3	2	0	3	3	
	23	Addenbrookes	2	176	15	9	0	15	13	
	107	Glasgow	2	124	5	4	0	5	4	
	63	Guy's	3	176	4	2	0	4	3	
	105	Oxford	3	120	6	5	0	6	5	
	40	Royal Free	4	176	0	0	1	1	1	
	2	Addenbrookes	5	176	37	21	0	37	32	
	19	Bristol	6	176	1	1	0	1	1	
	96	Newcastle	6	176	7	4	0	7	6	
	93	Glasgow	7	52	1	2	0	1	1	
	31	Cardiff	Tissue bank	176	21	12	1	22	19	
	36	Coventry	Tissue bank	176	13	7	0	13	11	
	Total					113		2	115	100

Table 3 Abdominal organs received by study from 1 January to 31 July 2021 (ctd.)

Organ	Study Number	Location	Ranking as at October 2021	Organs offered through NAS	Organs received through NAS		Organs received outside NAS	Total organs received	
				N	N	% of offered	N	N	%
Pancreas and islets	20	Newcastle	1	83	2	2	2	4	9
	85	Edinburgh	2	83	1	1	0	1	2
	3	Addenbrookes	3	83	27	33	0	27	57
	82	Oxford	3	83	2	2	0	2	4
	91 ¹	Oxford/Newcastle	4	83	6	7	0	6	13
	45	Oxford	6	6	1	17	0	1	2
	Unknown			0	0	0	6	6	13
Total					39		8	47	100
Total abdominal organs					221		11	232	100

NOTES

¹ One pancreas received through NAS were used for both study 3 and 91

CONCLUSION

- 18 Overall, the total number of untransplantable organs has steadily increased over time. In addition, the proportion of these organs that have consent/authorisation for research has increased to 97% for 2021 so far.
- 19 Since 2015, the number of untransplantable organs used for research has been decreasing each year to 400 in 2018 before an increase to 507 in 2019. In 2020, 299 organs were used for research, which was lower than usual due to the coronavirus pandemic. The number of organs used for research has increased again to 265 organs in 2021 so far.
- 20 The proportion of discarded organs where generic research consent/authorisation was ascertained is substantially higher than in previous years; 13% in 2015 compared to 39% for the period January to July 2021. However, the rate is lower than the previous three years.
- 21 During the period January to July 2021, 511 retrieved but untransplanted organs were offered to researchers through the National Allocation Scheme. 254 of the 511 organs offered for research were accepted by studies on the ODT Research Registry. 69% of organs were offered outside of core hours or over weekends and bank holidays. 59% of organs offered during core hours were accepted, 44% offered outside of core hours were accepted and 38% of organs offered over weekends and bank holidays were accepted.
- 22 In addition to these 254 organs used for research, an additional 11 were used but were not offered through the NAS.
- 23 Utilised research organs were distributed across many studies which suggests that studies that were ranked lower through the allocation scheme were still able to obtain research organs.

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October 2021

APPENDIX – Research studies ranking, October 2021

Organ	Study	Rank	Start date	End date	Location	Study Title
Heart	83	1	2019	2022	Newcastle	Evaluation of Hypothermic Oxygenated Perfusion (HOP) Ex-Vivo Heart Perfusion to Expand the Donor Pool and Improve Transplant Outcomes
Heart	90	2	2020	2022	Newcastle	Quality in Organ Donation: QUOD-MRC - Expansion to include Whole-Organ Collection and Research of Heart, Lung, Pancreas, Kidney and Liver: Heart Atlas Project
Heart	67	3	2017	2022	Imperial	Structural and functional analysis of intact myocardium and isolated cells from explanted hearts
Heart	118	4	2021	2024	Newcastle	Development of a human precision cut slice (PCS) model to study cardiac inflammation and fibrosis
Lungs	66	1	2017	2022	Newcastle	Further Evaluation of Ex Vivo Lung Perfusion to Improve Transplantation Outcomes
Lungs	58	2	2017	2025	Edinburgh	Multiplexed Optical Molecular Imaging and Sensing during Ex Vivo Lung Perfusion (EVLP)
Lungs	101	3	2020	2022	Newcastle	Quality in Organ Donation: QUOD-MRC - Expansion to include Whole-Organ Collection and Research of Heart, Lung, Pancreas, Kidney and Liver: Lung Atlas Project
Liver	21	1	2014	2021	Addenbrookes	Development of pre-transplant normothermic perfusion reconditioning for human livers donated after circulatory death
Liver	35	3	2014	2024	Birmingham	Normothermic Liver Perfusion
Liver	68	3	2017	2022	King's	Hepatocyte Transplantation Project: Studies on isolated hepatocytes. Note: There are 5 sub-studies to this one including Study 77 and Study 78
Liver	56	5	2016	2022	Edinburgh	Human Hepatic Progenitor Cells as a Source of Liver Regeneration
Liver	102	6	2020	2022	Oxford	High-risk steatotic donor livers in the era of normothermic machine perfusion: Application of novel therapies to achieve transplantability criteria
Liver	103	6	2021	2022	King's	Role of Mesenchymal Stem Cells in reducing Ischaemia Reperfusion Injury and immunogenicity after Liver Transplantation
Liver	105	6	2021	2025	Oxford	Investigating the use of normothermic perfused organs for organ assessment, preservation, modification and therapy
Liver	84	7	2019	2023	Birmingham	Investigating how inflammation determines the development and outcome of inflammatory liver diseases, and whether new targets for drug therapies can be identified
Liver	86	7	2020	2024	Birmingham	Understanding the mechanisms that drive development and resolution of liver and bowel fibrosis

APPENDIX – Research studies ranking, October 2021

Organ	Study	Rank	Start date	End date	Location	Study Title
Kidney	48	1	2015	2023	Newcastle	Establishing ex vivo normothermic perfusion (EVNP) of kidneys for transplantation
Kidney	23	2	2012	2022	Addenbrookes	Characterisation of ischaemia reperfusion injury in human kidneys
Kidney	107	2	2021	2022	Glasgow	DELIVERY OF ADIPOSE-DERIVED REGENERATIVE CELL THERAPY DURING EX-VIVO NORMOTHERMIC PERFUSION OF KIDNEYS
Kidney	63	3	2016	2021	Guy's	Transplanting the untransplantable - extending antibody incompatible transplantation using a normothermic perfusion model with cytoprotective agents
Kidney	105	3	2021	2025	Oxford	Investigating the use of normothermic perfused organs for organ assessment, preservation, modification and therapy
Kidney	40	4	2014	2024	Royal Free	Identification of genes involved in renal, electrolyte and urinary tract disorders
Kidney	2	5	2012	2026	Addenbrookes	Study of renal ischaemia-reperfusion injury and its amelioration. Note: This study has now been split into separate parts to allow the team to accept organs with restrictions
Kidney	19	6	2006	2021	Bristol	Establishment of cultured human glomerular cells for study of glomerular function in vitro
Kidney	96	6	2020	2022	Newcastle	Development of a human precision cut slice (PCS) model to study renal inflammation and fibrosis
Pancreas	20	1	2005	2022	Newcastle	Process development for islet isolation targeted at enhancing islet yield and viability.
Pancreas	85	2	2019	2022	Edinburgh	Use of deceased donor pancreata to optimise and improve the clinical islet isolation process in a research environment
Pancreas	3	3	2012	2026	Addenbrookes	Study of Pancreas Function, Physiology, Pathology and Therapeutics. Note: This study has now been split into separate parts to allow the team to accept organs with restrictions
Pancreas	82	3	2019	2022	Oxford	Development of an ex-vivo endocrine pancreas for the investigation and treatment of diabetes
Pancreas	91	4	2020	2022	Oxford/Newcastle	Quality in Organ Donation: QUOD-MRC - Expansion to include Whole-Organ Collection and Research of Heart, Lung, Pancreas, Kidney and Liver: Pancreas & Islet Atlas Project
Pancreas	45	6	2009	2021	Oxford	Studies of Factors Influencing the Structure and Function of Human Pancreatic Islets for Transplantation
Kidney	48	1	2015	2023	Newcastle	Establishing ex vivo normothermic perfusion (EVNP) of kidneys for transplantation
Kidney	23	2	2012	2022	Addenbrookes	Characterisation of ischaemia reperfusion injury in human kidneys