

NHS BLOOD AND TRANSPLANT**PANCREAS ADVISORY GROUP****ISLET TRANSPLANT ACTIVITY AND OUTCOME
SUMMARY****INTRODUCTION**

- 1 Islet transplant data has been collected by NHSBT since the introduction of four transplant and follow-up forms in July 2010. This paper provides summaries of transplant activity and outcomes, including 28-day follow-up which was introduced in January 2023 following PAG approval.

DATA

- 2 Islet transplant activity, including simultaneous islet and kidney (SIK) grafts, and end of year transplant list for the last three calendar years were analysed. Data on 208 routine, and subsequent priority, islet transplants performed in the UK between 1 April 2010 and 31 December 2022 were analysed from the UKTR. Outcome data are reported for routine transplants only.

RESULTS

- 3 In 2023 there were 21 islet transplants performed, of which eight were SIK. There were 35 patients on the islet transplant list at 31 December 2023, 30 routine (18 SIK) and five priority patients.
- 4 One-year graft survival for first routine islet alone grafts is 84% for transplants performed 1 January 2016 to 31 December 2022. There is a significant difference in five-year graft survival for those receiving a routine and priority top-up graft compared with those receiving a routine only graft, 64% and 40%, respectively $p=0.0002$.
- 5 For patients receiving an islet alone routine and a priority graft, the median annual rate of severe hypoglycaemic events fell from 9 events (IQR 0 – 43) at time of transplant, to none at one, two, three and five years' post-transplant. Of all routine islet transplants, 111 (85%) experienced no severe hypoglycaemic events in the first-year post-transplant.
- 6 Median HbA1c fell from 64 mmol/mol (IQR 55 – 76) at time of transplant, to 51 mmol/mol (IQR 42 – 58) at one year and 55 (IQR 47 – 64) at three years post-transplant, for patients who received a routine and a priority graft. Overall, a reduction in HbA1c was reported for 105 (82%) patients at one-year post-transplant.
- 7 The median insulin dose, for patients who received routine and priority grafts, fell from 0.51 units/kg (IQR 0.38 – 0.625) at time of transplant to 0.295 units/kg (IQR 0.17 – 0.49) three years post-transplant. Insulin independence at some point in the first-year post-transplant was achieved for 35% of patients overall where reported.

SUMMARY

- 8 In 2023, the number of islet transplants and patients on the waiting list at the end of the year have increased. One-year graft survival is 84% for transplants performed between 1 January 2016 and 31 December 2022. The median annual rate of severe hypoglycaemic events, HbA1c and insulin dose at one-year, two, three and five years post routine transplant are lower than pre-transplant.

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- 9 Islet transplant data has been collected by NHSBT since the introduction of four transplant and follow-up forms in July 2010. This paper provides basic summaries of transplant activity and outcomes, including 28-day follow-up.

DATA

- 10 Recent data on islet transplant activity, including simultaneous islet and kidney (SIK) grafts, and end of year transplant list between 1 January 2021 and 31 December 2023 from the UK Transplant Registry (UKTR) are reported, by centre and calendar year.
- 11 Between 1 April 2010 and 31 December 2022, there were 208 routine islet transplants performed in the UK. Outcome data on these 208 routine, and any subsequent priority, islet transplants have been analysed from the UKTR. Outcome data are reported for routine transplants only. Where outcome data are unavailable from UKTR, data collected by the UKITC clinical research forms have been considered. These data have been provided by the Newcastle research group who collate and maintain the research data base.
- 12 All islet transplant outcome data reported are specific to the routine transplant and one-year centre specific outcomes are presented in the Appendix.

RESULTS

- 13 The number of islet transplants performed by centre for the last three calendar years, 1 January 2021 to 31 December 2023, is shown by transplant type and islet status in **Tables 1** and **2**, respectively. **Table 3** shows the transplant list at the end of the last three calendar years by islet status.
- 14 Between 1 April 2010 and 31 December 2022, there were a total of 325 islet transplants performed, 208 (64%) of which were routine (including 35 SIK transplants) and 117 were priority. One patient received only a priority transplant in this time period as their routine transplant was before 1 April 2010.
- 15 For those patients receiving a routine transplant between 1 April 2010 and 31 December 2022, the number of known graft failures at one-year post-transplant is reported in **Table 4**. Of the 208 routine transplants performed, 115 patients subsequently received a priority graft. The majority of these patients received their first priority graft within six months of their routine graft: 0-3 months for 34 (30%) patients; 3-6 months for 41 (36%) patients; 6-12 months for 38 (33%) patients and more than one year for two patients who were highly sensitised.

Table 1 UK islet transplant activity between 1 January 2021 and 31 December 2023, by transplant type and calendar year

Transplant Centre	2021							2022							2023						
	ITA	IAK	IAP	IAPK	SIK	Total		ITA	IAK	IAP	IAPK	SIK	Total		ITA	IAK	IAP	IAPK	SIK	Total	
						N	%						N	%						N	%
Bristol	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Edinburgh	7	2	0	0	3	12	52	6 ¹	3 ¹	0	0	2 ¹	11	65	3 ¹	2	0	0	3 ³	8	38
King's	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Manchester	0	1 ¹	0	0	3 ²	4	17	0	2	0	0	3	5	29	1	1	0	0	5 ²	7	33
Newcastle	3	2	0	0	0	5	22	1	0	0	0	0	1	6	3	0	0	0	0	3	14
Oxford	1 ¹	0	0	0	1	2	9	0	0	0	0	0	0	0	1	1	0	1	0	3	14
Royal Free	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TOTAL	11	5	0	0	7	23	100	7	5	0	0	5	17	100	8	4	0	1	8	21	100

ITA = Islet transplant alone IAK = Islet after kidney IAP = Islet after pancreas IAPK = Islet after simultaneous pancreas/ kidney
 SIK = Simultaneous islet/kidney

¹ Includes 1 DCD transplant

² Includes 2 DCD transplants

³ Includes 3 DCD transplants

Table 2 UK islet transplant activity between 1 January 2021 and 31 December 2023, by islet status, number of patients and calendar year

Transplant Centre	2021								2022								2023							
	Routine Islet alone		Priority	Total		Number of patients		Routine Islet alone		Priority	Total		Number of patients		Routine Islet alone		Priority	Total		Number of patients				
	SIK	N	%	N	%	N	%	SIK	N	%	N	%	N	%	SIK	N	%	N	%	N	%			
Bristol	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
Edinburgh	5	3	4	12	52	9	47	4	2	5	11	65	8	57	4	3	1	8	38	8	40			
King's	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
Manchester	0	3	1	4	17	4	21	0	3	2	5	29	5	36	1	5	1	7	33	7	35			
Newcastle	4	0	1	5	22	4	21	1	0	0	1	6	1	7	1	0	2	3	14	2	10			
Oxford	1	1	0	2	9	2	11	0	0	0	0	0	0	0	3	0	0	3	14	3	15			
Royal Free	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
TOTAL	10	7	6	23	100	19	100	5	5	7	17	100	14	100	9	8	4	21	100	20	100			

Table 3 UK islet transplant list, 31 December 2021 to 31 December 2023, by islet status and calendar year

Transplant Centre	31 December 2021					31 December 2022					31 December 2023				
	Routine		Priority	Total		Routine		Priority	Total		Routine		Priority	Total	
	Islet alone	SIK		N	%	Islet alone	SIK		N	%	Islet alone	SIK		N	%
Bristol	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Edinburgh	6	3	4	13	39	2	0	1	3	14	4	5	4	13	37
King's	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Manchester	1	6	2	9	27	0	8	0	8	36	1	6	1	8	23
Newcastle	5	1	3	9	27	7	1	0	8	36	5	0	0	5	14
Oxford	1	0	1	2	6	1	2	0	3	14	2	7	0	9	26
Royal Free	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TOTAL	13	10	10	33	100	10	11	1	22	100	12	18	5	35	100

Table 4 One-year graft outcome following routine islet transplant, 1 April 2010 to 31 December 2022			
Number of grafts	No. of transplants	No. with known outcome at one year	No. with known graft failure at one year
Islet routine graft			
Routine only	71	63	16
Routine and one priority graft	101	96	6
Routine and two priority grafts	1	1	0
SIK routine graft			
Routine only	22	15	4
Routine and one priority graft	13	10	0
Routine and two priority grafts	0	0	0
Total	208	185	26

Figure 1a One-year graft function by total IEQ per kg recipient body weight for islet alone routine only grafts, 1 April 2010 to 31 December 2022

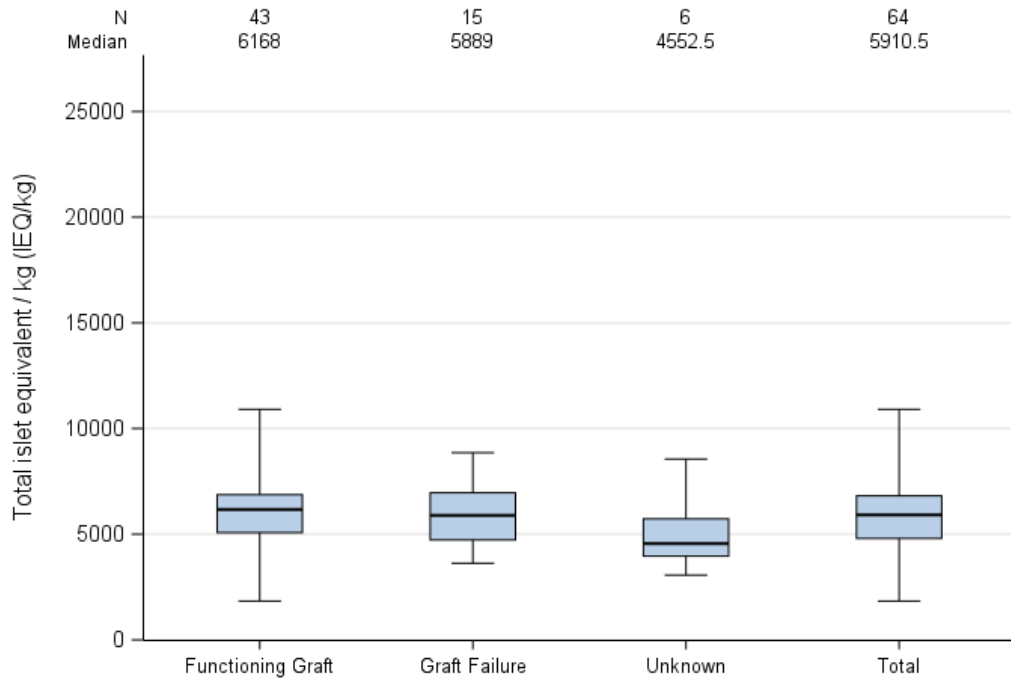


Figure 2a One-year graft function by total IEQ per kg recipient body weight for islet alone routine and priority grafts, 1 April 2010 to 31 December 2022

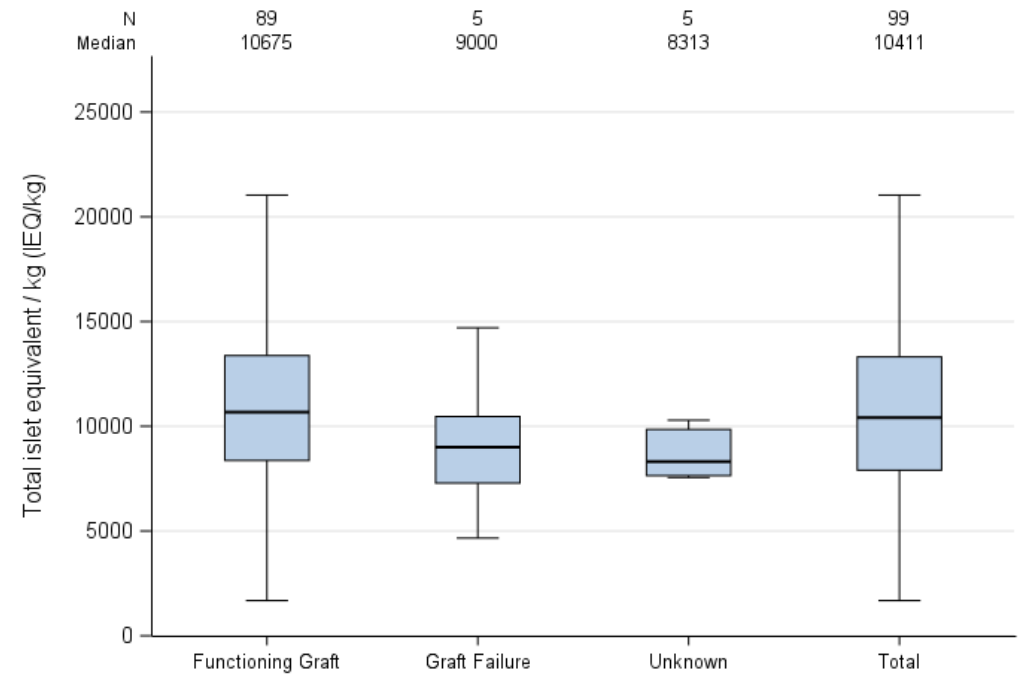


Figure 1b One-year graft function by total IEQ per kg recipient body weight for islet alone routine only grafts, 1 January 2016 to 31 December 2022

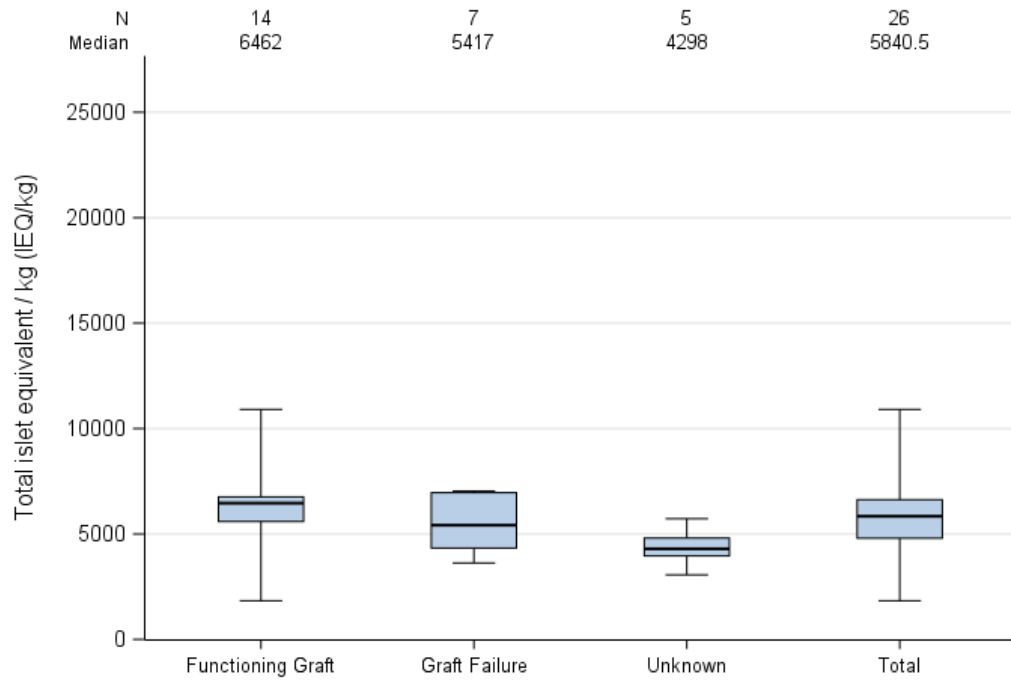
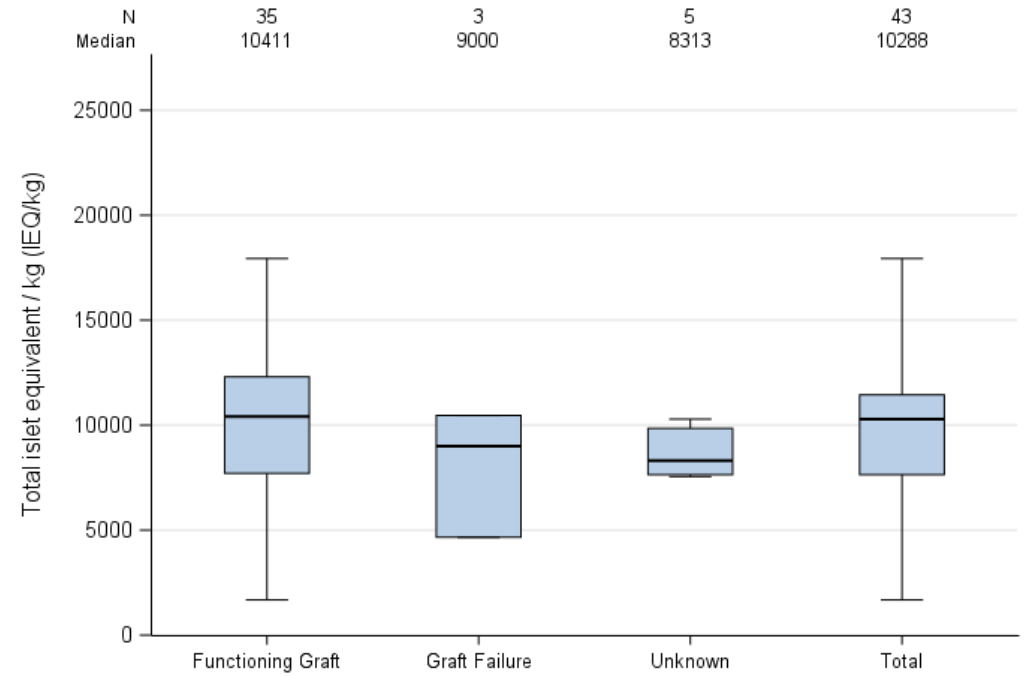


Figure 2b One-year graft function by total IEQ per kg recipient body weight for islet alone routine and priority grafts, 1 January 2016 to 31 December 2022



- 16 One-year graft outcome by total IEQ per kg (IEQx1000/kg) transplanted is presented in **Figures 1a** and **2a**, for the whole time period for islet alone routine only and routine and priority grafts, respectively. **Figures 1b** and **2b** show the data for transplants in the recent time period, 1 January 2016 to 31 December 2022. The median total IEQ per kg transplanted for 17 SIK routine only transplants was 4063 (IQR 2724 - 5000) and for 13 SIK routine and priority grafts was 8047 (IQR 7015 – 10526). This was lower than the median for islet alone transplants in both groups.
- 17 Kaplan-Meier survival plots showing one-year and five-year graft survival after first routine islet alone transplants are presented in **Figure 3** and **Figure 4**, respectively. One year graft survival is 89%, 95% CI (81-94%) for transplants performed between 1 April 2010 and 31 December 2015 and 84%, 95% CI (72-92%) for transplants performed between 1 January 2016 and 31 December 2022, and was not statistically significantly different ($p=0.43$). Five year graft survival is 54%, 95% CI (43-63%) for transplants performed between 1 April 2008 and 31 December 2015 and 65%, 95% CI (49-77%) for transplants performed between 1 January 2016 and 31 December 2022, $p=0.59$.
- 18 **Figure 5** shows a Kaplan-Meier survival plot of five-year graft survival by type of graft. Estimated five-year graft survival for first routine only grafts is 40%, 95% CI (27-53%) and for first routine grafts followed by a priority graft is 64%, 95% CI (53-73%). This difference was statistically significant, $p=0.0002$.
- 19 **Figure 6** shows a Kaplan-Meier survival plot of five-year graft survival by type of graft, where the first routine graft was still functioning at one-year post-transplant. Estimated five-year graft survival for routine only grafts is 55%, 95% CI (37-69%) and for routine grafts followed by a priority graft is 68%, 95% CI (56-77%). This difference was not statistically significant, $p=0.1054$.
- 20 **Figure 7** shows a Kaplan-Meier survival plot of five-year patient survival after first routine islet alone transplant. Five year patient survival is 93%, 95% CI (85-96%).
- 21 Of the 35 SIK islet transplants in the 1 April 2010 to 31 December 2022 time period, 33 were the first islet transplant for the patient. Of these 33, follow-up information was available for 30 and the estimated one-year graft survival rate is 86%, 95% CI (67-95%).

Figure 3 One-year graft survival following first routine islet alone transplantation performed in the UK between 1 April 2010 and 31 December 2022, by when transplant was performed

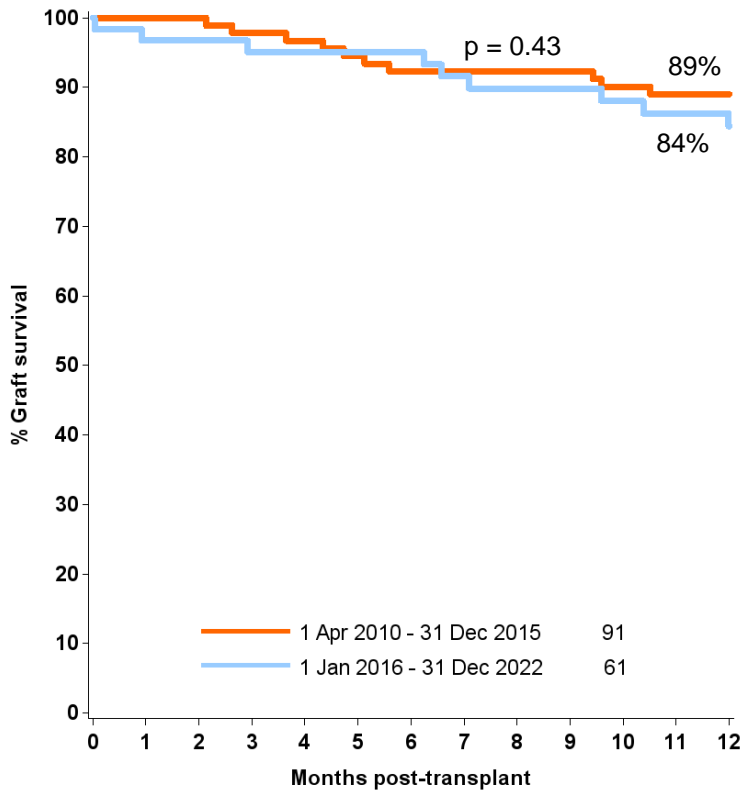


Figure 4 Five-year graft survival following first routine islet alone transplantation performed in the UK between 1 April 2008 and 31 December 2022, by when transplant was performed

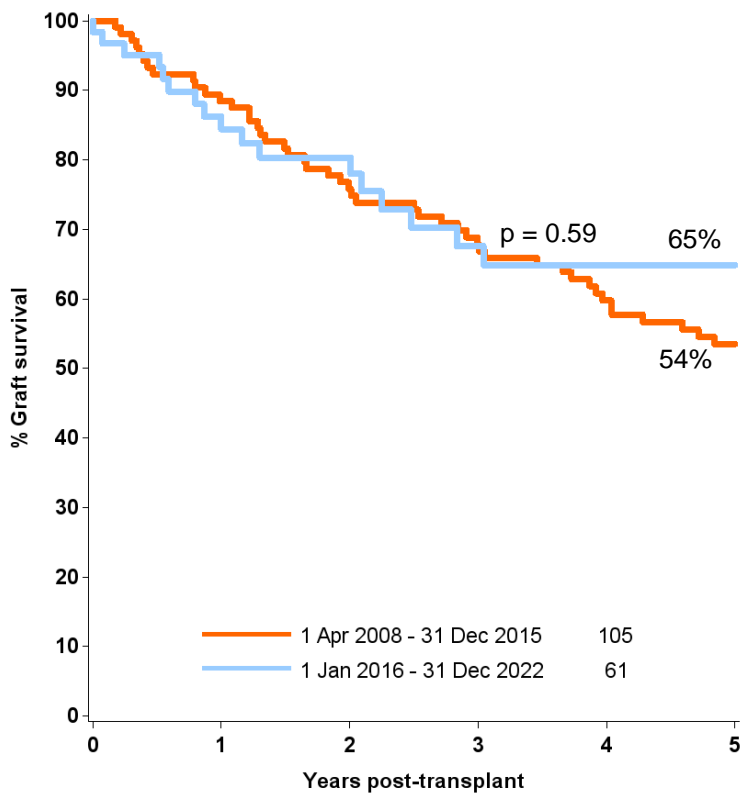


Figure 5 Five-year graft survival following first routine islet alone transplantation performed in the UK between 1 April 2008 and 31 December 2022, by type of graft

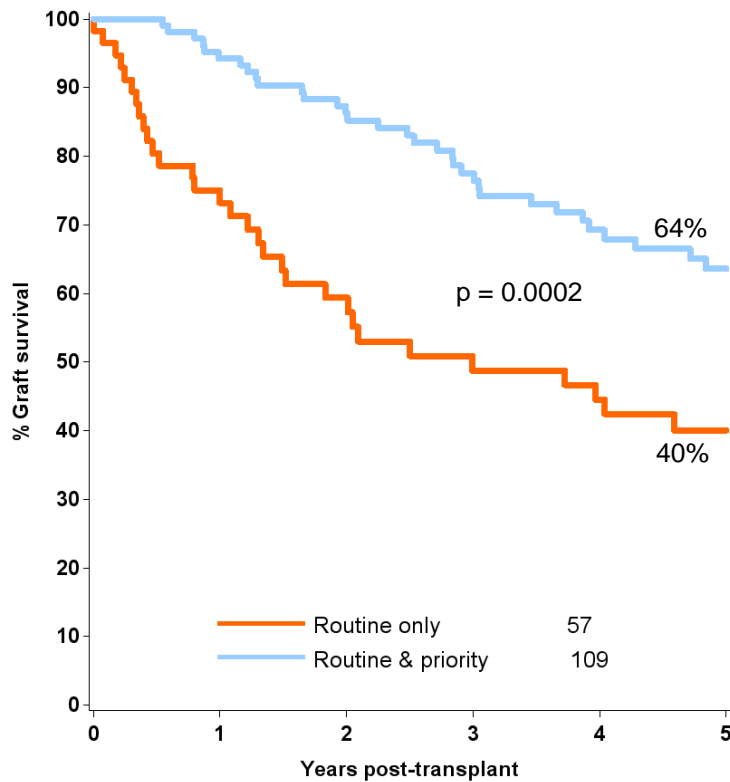


Figure 6 Five-year graft survival following first routine islet alone transplantation where the routine graft was functioning at one year in the UK between 1 April 2008 and 31 December 2022, by type of graft

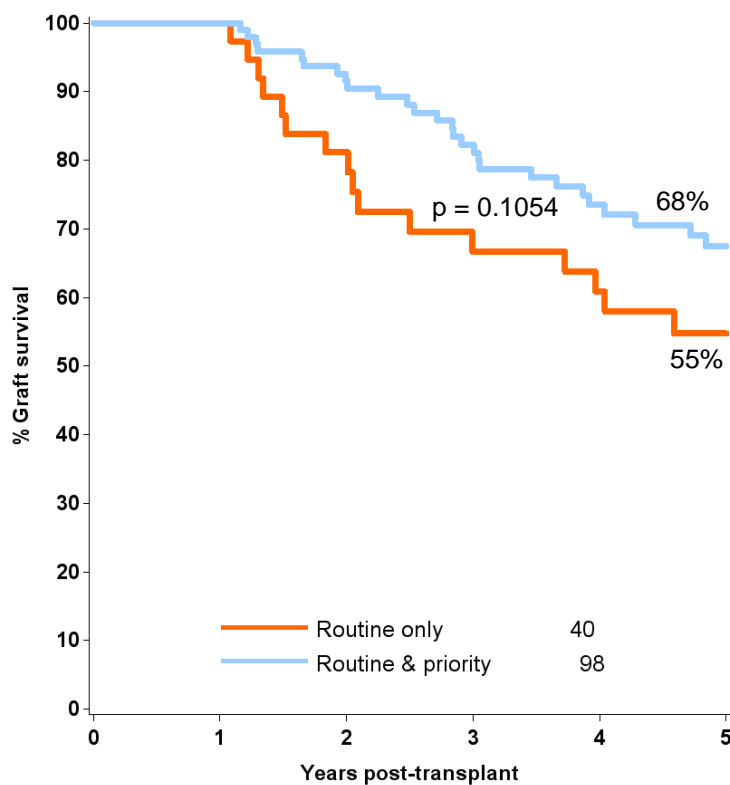
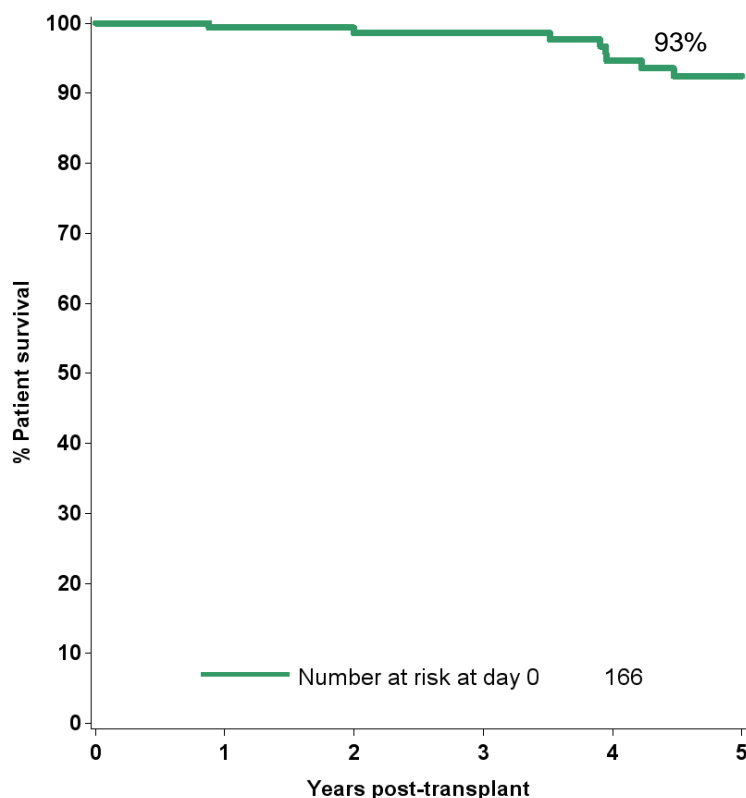


Figure 7 Five-year patient survival following first routine islet alone transplantation performed in the UK between 1 April 2008 and 31 December 2022



- 23 **Figures 8 and 9** show the median rate of severe hypoglycaemic events, excluding SIK transplants, for routine only grafts and for routine and priority grafts, respectively. Overall, at one-year post-transplant data were available in 130 cases, 111 (85%) patients experienced no severe hypoglycaemic events during the first year following their routine transplant, whilst 19 (15%) patients experienced between one and five events. Of 123 cases where it could be calculated, 84 (68%) patients had a reduced number of events at one year post-transplant.
- 24 For the 29 SIK transplants where severe hypoglycaemic events were reported at transplant, the median rate was 2 (IQR 0-41) and for the 19 reported at one-year post-transplant, the median rate was 0 (IQR 0-0).
- 25 Median HbA1c is reported in **Figure 10** for routine only grafts and **Figure 11** for routine and priority grafts, excluding SIK transplants. Overall, data were available to calculate the reduction in HbA1c in 128 cases at one-year post-transplant and in 105 (82%) patients a reduction in HbA1c was reported. The proportion of patients with HbA1c of less than 53 mmol/mol was 17% of 161 at time of transplant, 56% of 138 patients at one-year post-transplant, 39% of 89 patients at three years and 37% of 51 patients at five years post-transplant.
- 26 For the 30 SIK transplants where HbA1c was reported at transplant, the median was 62 mmol/mol (IQR 55-73) and for the 18 reported at one-year post-transplant, the median was 55 mmol/mol (IQR 45-61).

Figure 8 Median annual rate of severe hypoglycaemic events post-transplant for routine only grafts, 1 April 2010 – 31 December 2022 (excluding SIK transplants)

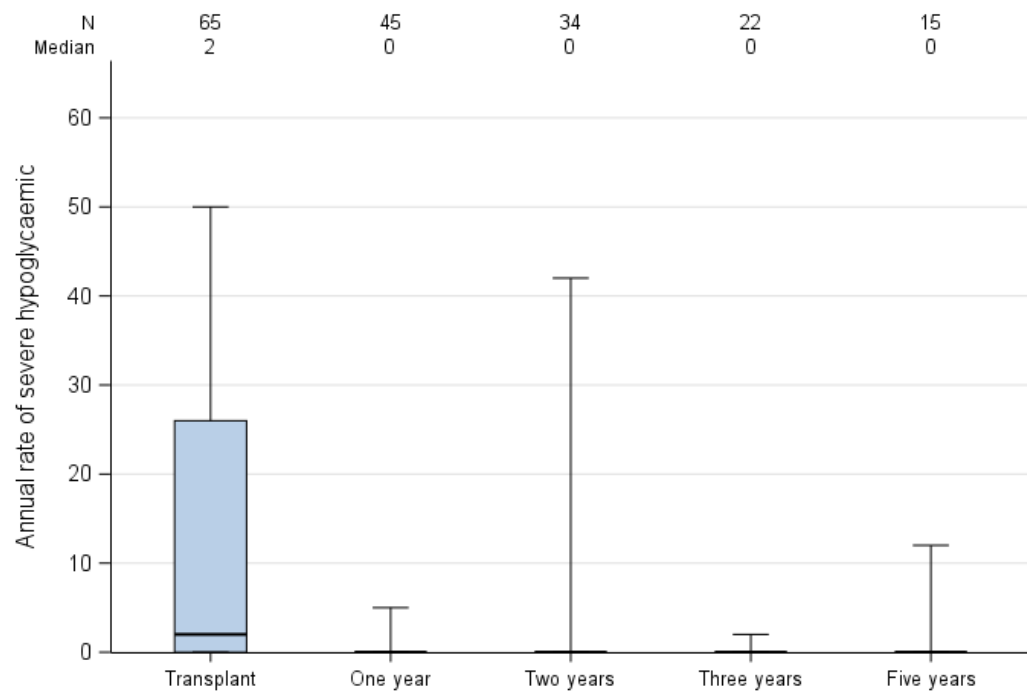


Figure 9 Median annual rate of severe hypoglycaemic events post-transplant for routine and priority grafts, 1 April 2010 – 31 December 2022 (excluding SIK transplants)

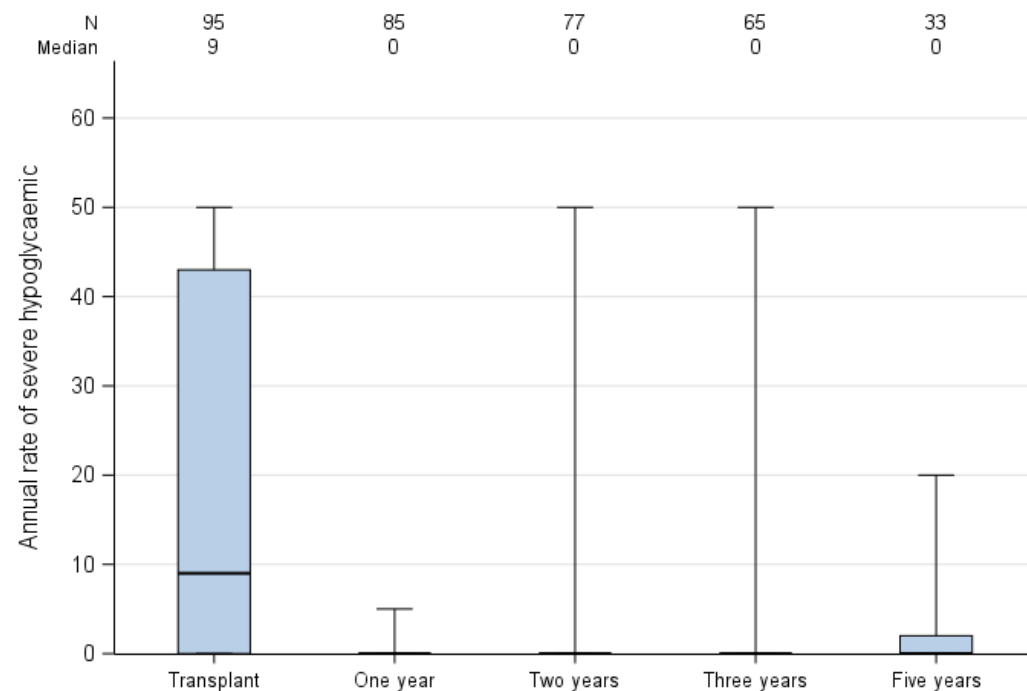


Figure 10 Median HbA1C post-transplant for routine only grafts, 1 April 2010 – 31 December 2022 (excluding SIK transplants)

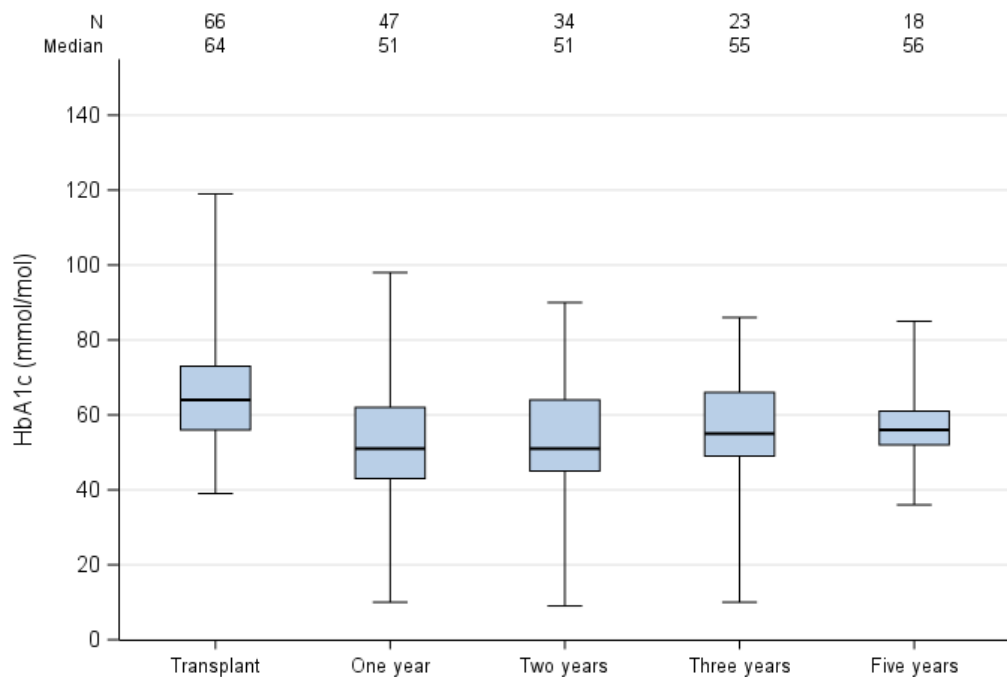


Figure 11 Median HbA1C post-transplant for routine and priority grafts, 1 April 2010 – 31 December 2022 (excluding SIK transplants)

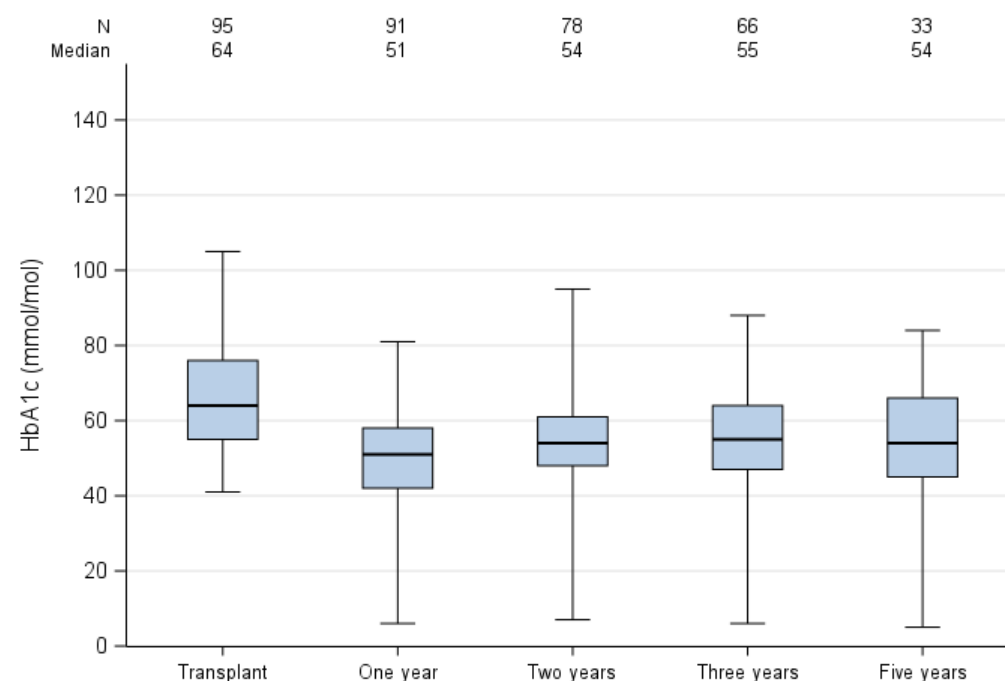


Figure 12 Median insulin dose post-transplant for routine only grafts, 1 April 2010 – 31 December 2022 (excluding SIK transplants)

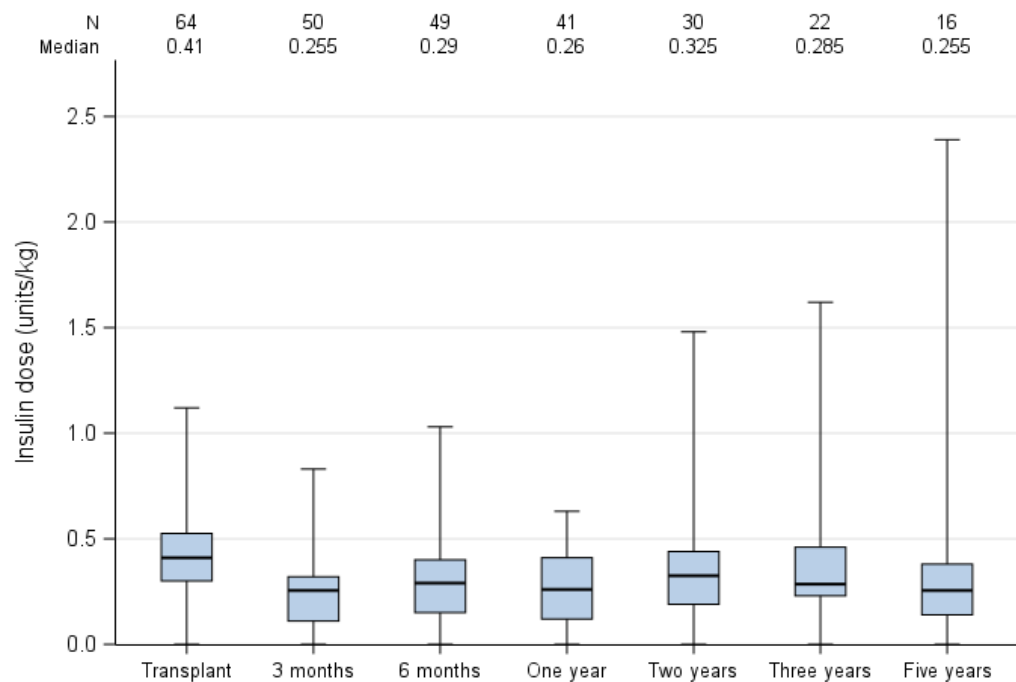
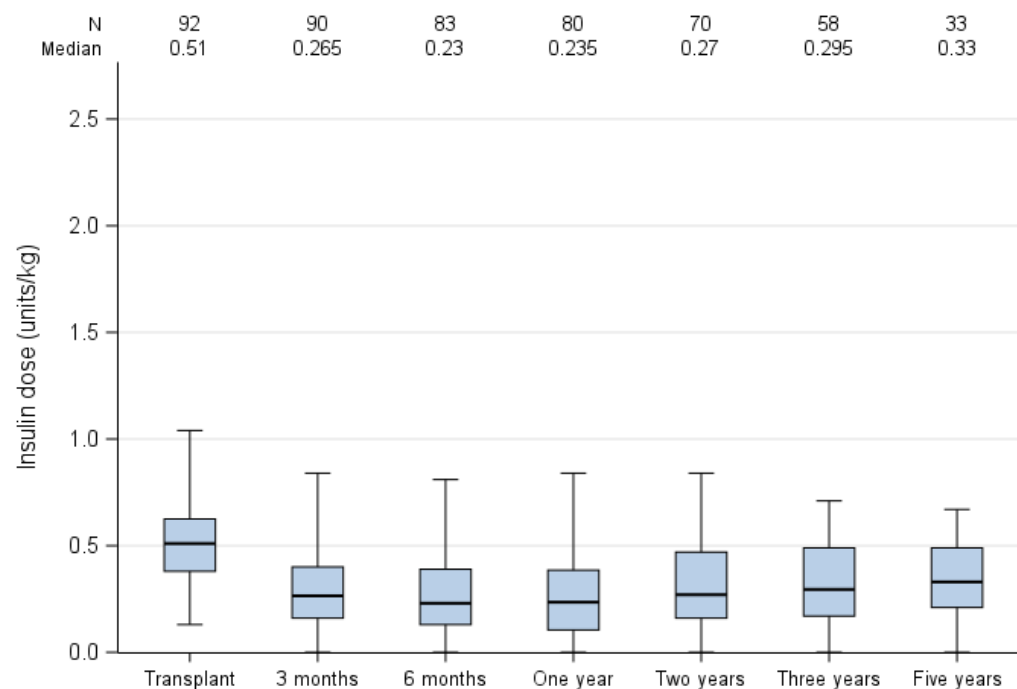


Figure 13 Median insulin dose post-transplant for routine and priority grafts, 1 April 2010 – 31 December 2022 (excluding SIK transplants)



- 27 **Figure 12** and **Figure 13** show the median insulin dose for routine only grafts and routine and priority grafts, respectively, excluding SIK transplants. Overall, in 115 patients where the difference in insulin dose between transplant and one-year post-transplant could be calculated, 102 (89%) reported a reduction. Of the 129 patients with insulin independence status reported for the first-year post-transplant, 45 (35%) achieved insulin independence at some point in the year.
- 28 For the 30 SIK transplants where insulin dose was reported at transplant, the median was 0.48 units/kg (IQR 0.35-0.7) and for the 18 reported at one-year post-transplant, the median was 0.34 units/kg (IQR 0.24-0.49).
- 29 The 28-day islet follow-up form was introduced on 1st January 2022. As at 22nd February 2024, 36 follow-up forms had been received. There were 23 routine and 13 priority top-up grafts reported.

SUMMARY

- 30 In 2023, the number of islet transplants and patients on the waiting list at the end of the year have increased.
- 31 One-year graft survival is 84% for transplants performed between 1 January 2016 and 31 December 2022 and 89% for the earlier cohort between 1 April 2010 and 31 December 2015. Five-year graft survival was 54% overall between 1 January 2016 and 31 December 2022. Those patients receiving a routine and a priority top-up graft had significantly better five-year graft survival than those receiving a routine only, 64% and 40%, respectively, $p=0.0002$.
- 32 The median annual rate of severe hypoglycaemic events, HbA1c and insulin dose at one-year, two, three and five years post routine transplant were lower than at pre-transplant.

APPENDIX

Table I		Islet graft function at one year post transplant by transplant centre, 1 April 2010 to 31 December 2022				
Transplant centre	Routine transplants performed	Priority transplants performed (% of routine)		Graft function at one year following routine transplant in the time period		
				No. with known outcome	Graft failure (% of known outcome)	Priority grafts with graft failure
Bristol	3	1	(33)	3	0 (0)	0
Edinburgh	79	55	(70)	70	8 (11)	4
King's College	11	7	(64)	10	2 (20)	0
Manchester	28	15	(54)	23	3 (13)	0
Newcastle	38	17	(45)	34	3 (9)	0
Oxford	38	17	(45)	34	9 (26)	2
Royal Free	11	5	(45)	11	1 (9)	0
Total	208 ¹	117	(56)	185 ²	26 ³ (14)	6

¹ Includes 35 SIK transplants: Edinburgh (13), Manchester (19), Newcastle (1), Oxford (2)
² Includes 25 SIK transplants: Edinburgh (9), Manchester (14), Newcastle (1), Oxford (1)
³ Includes 4 SIK transplants: Edinburgh (2), Manchester (2)

Transplant centre	Routine transplant s (one-year data expected ²)		At registration			Annual rate of severe hypoglycaemic events						Reduction ³	No. with reduced events	Reduction not calculated ⁴		
	N	(N)	N	Median	(IQ range)	N	Median	(IQ range)	N	Median	(IQ range)				N	Median
Bristol	3	3	3	2	(2 - 3)	3	3	(2 - 50)	3	0	(0 - 0)	3	3	(2 - 50)	3	0 (0)
Edinburgh	66	63	56	35	(7 - 50)	62	28	(8 - 50)	53	0	(0 - 0)	49	32	(8 - 50)	43	14 (22)
King's College	11	9	9	4	(2 - 16)	11	3	(0 - 16)	6	0	(0 - 0)	6	2	(0 - 50)	3	3 (33)
Manchester	9	8	6	5	(1 - 8)	9	3	(1 - 8)	8	0	(0 - 0)	8	4	(1 - 9)	6	0 (0)
Newcastle	37	35	22	10	(2 - 25)	37	18	(2 - 29)	27	0	(0 - 1)	27	8	(1 - 28)	23	8 (23)
Oxford	36	33	7	3	(1 - 4)	28	0	(0 - 1)	24	0	(0 - 0)	21	0	(0 - 0)	5	12 (36)
Royal Free	11	10	3	4	(0 - 8)	10	0	(0 - 0)	9	0	(0 - 0)	9	0	(0 - 0)	1	1 (10)
Total	173	161	106	10	(3 - 50)	160	8	(0 - 33)	130	0	(0 - 0)	123	7	(0 - 37)	84	38 (24)

¹ Excluding SIK transplants
² Follow-up reported or graft not known to have failed
³ Between transplant and one-year
⁴ Information missing at either transplant or one-year out of those where expected

Transplant centre	Routine transplants (one-year data expected ²)		At transplant			HbA1c mmol/mol At one-year			Reduction ³			No. with lower HbA1c N	Reduction not calculated ⁴ N (%)
	N	(N)	N	Median	(IQ range)	N	Median	(IQ range)	N	Median	(IQ range)		
Bristol	3	3	3	68	(53 - 70)	3	56	(33 - 81)	3	0	(0 - 37)	1	0 (0)
Edinburgh	66	63	61	62	(53 - 71)	55	53	(46 - 63)	50	6	(1 - 13)	38	13 (21)
King's College	11	9	11	70	(55 - 86)	6	42	(10 - 45)	6	26	(9 - 87)	6	3 (33)
Manchester	9	8	9	64	(57 - 75)	8	45	(43 - 47)	8	18	(8 - 36)	8	0 (0)
Newcastle	37	35	37	73	(62 - 83)	29	51	(42 - 58)	29	17	(13 - 28)	25	6 (17)
Oxford	36	33	29	62	(55 - 69)	28	50	(42 - 58)	23	15	(8 - 25)	21	10 (30)
Royal Free	11	10	11	61	(56 - 86)	9	51	(43 - 57)	9	4	(0 - 20)	6	1 (10)
Total	173	161	161	64	(55 - 75)	138	51	(43 - 59)	128	12	(3 - 21)	105	33 (20)

¹ Excluding SIK transplants

² Follow-up reported or graft not known to have failed

³ Between transplant and one-year

⁴ Information missing at either transplant or one-year out of those where expected

Table IV Reduction in insulin dose per kg at one-year post transplant and insulin independent in first year post-transplant 1 April 2010 to 31 December 2022¹

Transplant centre	Routine transplants (one-year data expected ²)		At transplant			Insulin dose/kg At one-year			Reduction ³			No. insulin independent	Reduction not calculated ⁴
	N	(N)	N	Median	(IQ range)	N	Median	(IQ range)	N	Median	(IQ range)	N	N (%)
Bristol	3	3	3	0.42	(0.37 - 0.48)	3	0.20	(0.12 - 0.47)	3	0.22	(0.01 - 0.25)	1	0 (0)
Edinburgh	66	63	61	0.50	(0.38 - 0.61)	51	0.23	(0.10 - 0.39)	46	0.23	(0.14 - 0.36)	25	17 (27)
King's College	11	9	10	0.35	(0.22 - 0.42)	4	0.13	(0.07 - 0.21)	4	0.20	(0.15 - 0.27)	3	5 (56)
Manchester	9	8	9	0.52	(0.45 - 0.55)	8	0.28	(0.12 - 0.35)	8	0.27	(0.26 - 0.33)	3	0 (0)
Newcastle	37	35	36	0.44	(0.33 - 0.56)	25	0.29	(0.12 - 0.40)	25	0.19	(0.04 - 0.28)	5	10 (29)
Oxford	36	33	27	0.45	(0.32 - 0.62)	21	0.26	(0.14 - 0.38)	21	0.25	(0.06 - 0.43)	6	12 (36)
Royal Free	11	10	10	0.56	(0.40 - 0.80)	9	0.42	(0.24 - 0.50)	8	0.14	(0.01 - 0.35)	2	2 (20)
Total	173	161	156	0.47	(0.34 - 0.60)	121	0.25	(0.12 - 0.39)	115	0.23	(0.10 - 0.33)	45	46 (29)

¹ Excluding SIK transplants

² Follow-up reported or graft not known to have failed

³ Between transplant and one-year

⁴ Information missing at either transplant or one-year out of those where expected