NHS BLOOD AND TRANSPLANT
ORGAN DONATION AND TRANSPLANTATION DIRECTORATE

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. Data were collected retrospectively for all transplants since 1 April 2008 to ensure a complete data set since the commissioning of islet transplantation in the UK. This paper provides basic summaries of transplant activity and transplant outcomes.

DATA

2 Islet transplant activity and end of year transplant list for the last three calendar years were analysed. Data on 157 (99 routine and 58 priority) islet transplants performed in the UK where the routine transplant was performed between 1 April 2010 and 31 December 2015 were analysed from the UKTR. Outcome data are reported for all routine transplants.

RESULTS

3 In 2016, there were 29 islet transplants performed, three less than in 2015. 27 (93%) were islet transplant alone and Edinburgh performed the greatest proportion of transplants; 18 (62%). The number of patients on the islet transplant list at 31 December 2016 was 23, 17 routine and 6 priority, compared with 31 in 2015.

4 Kaplan-Meier estimated one-year graft survival for routine only grafts is 80%, 95% CI (64 - 90) and for the routine and priority grafts is 95%, 95% CI (84 - 98). There were statistically significant differences between the two groups $p<0.03$.

5 The median annual rate of severe hypoglycaemic events at time of transplant was 7 (IQR 0 - 34) and fell to none at one, two and three years post-transplant. 62 (78%) patients experienced no severe hypoglycaemic events in the first year post transplant.

6 Median HbA1c fell from 64mmol/mol (IQR 55 - 75) at time of transplant to 51mmol/mol (IQR 42 - 58) at one year and 54mmol/mol (IQR 48 - 63) at three years post-transplant. Reduction in HbA1c was reported for 71 (87%) patients at one year post-transplant.

7 The median insulin dose fell from 0.49 units/kg (IQR 0.33 - 0.60) at time of transplant to 0.25 units/kg at one year and 0.27 at three years post-transplant. A reduction in insulin was reported for 64 (90%) patients, of 71 cases where data were available.

SUMMARY

8 The number of islet transplants and patients on the transplant list at the end of the year fell slightly in 2016. Graft survival, reduction in rate of severe hypoglycaemic events, reduction in HbA1c and reduction in insulin dose at one, two and three year post routine transplant have been reported.

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INTRODUCTION

9 Islet transplant data has been collected by NHSBT since the introduction of four transplant and follow-up forms in July 2010. Data were collected retrospectively for all transplants since 1 April 2008 to ensure a complete data set since the commissioning of islet transplantation in the UK.

10 The recent increase in transplant activity and the continued efforts to improve form return rates have contributed to a small, but emerging national islet transplant registry. This paper provides basic summaries of outcomes.

DATA

11 Data on islet transplant activity and end of year transplant list between 1 January 2014 and 31 December 2016 from the UK Transplant Registry (UKTR) were analysed.

12 Data on 157 (99 routine and 58 priority) islet transplants performed in the UK where the routine transplant was performed between 1 April 2010 and 31 December 2015 were analysed from the UKTR. Outcome data are reported for all routine transplants. 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 database.

13 All islet transplant outcome data reported are specific to the routine transplant.

14 The four key measures of islet transplant outcome are:

i. Graft function
ii. Reduction in HbA1c (mmol/mol)
iii. Reduction in annual rate of severe hypoglycaemic events
iv. Reduction in insulin dose

All outcomes are reported at one-year, two-years and three-years post routine transplant.

Table 1 UK islet transplant activity between 1 January 2014 and 31 December 2016, by transplant type and calendar year

	2014						2015						2016					
					Total						Total						Total	
Transplant Centre	**ITA**	**IAK**	**IAP**	**IAPK**	**N**	**%**	**ITA**	**IAK**	**IAP**	**IAPK**	**N**	**%**	**ITA**	**IAK**	**IAP**	**IAPK**	**N**	**%**
Bristol	1	0	0	0	**1**	**4**	0	0	0	0	**0**	**0**	2	0	0	0	**2**	**7**
Edinburgh	6	0	0	1	**7**	**30**	16[3]	0	0	0	**16**	**50**	16[2]	2[1]	0	0	**18**	**62**
King's	1	0	0	0	**1**	**4**	1	0	0	0	**1**	**3**	3	0	0	0	**3**	**10**
Oxford	5	0	0	0	**5**	**22**	3	0	0	0	**3**	**9**	3[1]	0	0	0	**3**	**10**
Manchester	1	1	0	0	**2**	**9**	0	0	0	2	**2**	**6**	1	0	0	0	**1**	**3**
Newcastle	4[2]	1	0	0	**5**	**22**	7	1	0	0	**8**	**25**	2	0	0	0	**2**	**7**
Royal Free	2	0	0	0	**2**	**9**	2[1]	0	0	0	**2**	**6**	0	0	0	0	**0**	**0**
TOTAL	**20**	**2**	**0**	**1**	**23**	**100**	**29**	**1**	**0**	**2**	**32**	**100**	**27**	**2**	**0**	**0**	**29**	**100**

ITA = Islet transplant alone IAK = Islet after kidney IAP = Islet after pancreas IAPK = Islet after simultaneous kidney/pancreas
[1] Includes 1 DCD transplant [2] Includes 2 DCD transplants [3] Includes 5 DCD transplants

Table 2 UK islet transplant list, 31 December 2014 to 31 December 2016, by islet status and calendar year

	31 December 2014				31 December 2015				31 December 2016			
			Total				Total				Total	
Transplant Centre	**Routine**	**Priority**	**N**	**%**	**Routine**	**Priority**	**N**	**%**	**Routine**	**Priority**	**N**	**%**
Bristol	4	0	**4**	**11**	3	0	**3**	**10**	0	0	**0**	**0**
Edinburgh	14	2	**16**	**44**	11	3	**14**	**45**	3	1	**4**	**17**
King's	1	0	**1**	**3**	1	1	**2**	**6**	0	0	**0**	**0**
Oxford	3	0	**3**	**8**	2	0	**2**	**6**	8	1	**9**	**39**
Manchester	4	1	**5**	**14**	3	1	**4**	**13**	4	2	**6**	**26**
Newcastle	3	2	**5**	**14**	2	4	**0**	**19**	2	2	**4**	**17**
Royal Free	0	2	**2**	**6**	0	0	**0**	**0**	0	0	**0**	**0**
TOTAL	**29**	**7**	**36**	**100**	**22**	**9**	**31**	**100**	**17**	**6**	**23**	**100**

RESULTS

15 **Table 1** shows the number of islet transplants performed by each centre in the UK for the last three calendar years between 1 January 2014 and 31 December 2016 by transplant type. **Table 2** shows the number of patients on the islet transplant list at 31 December 2014, 31 December 2015 and 31 December 2016 by islet status.

16 A Kaplan-Meier survival plot showing one-year graft survival is presented in **Figure 1**. Estimated one-year graft survival for routine only grafts is 80%, 95% CI (64 – 90) and for the routine and priority grafts is 95%, 95% CI (84 - 98). There were statistically significant differences between the two groups $p<0.03$.

17 The median rate of severe hypoglycaemic events is presented in **Figure 2.** The median annual rate fell from 7 events (IQ range: 0 to 34) at time of transplant, to none (IQ range 0 to 0) at one, two and three years post-transplant. Data were available in 80 cases and 49 patients (61%) had a reduced number of events at one year post-transplant.

18 Sixty two patients, 78%, experienced no severe hypoglycaemic events during the first year following their routine transplant, whilst 18 patients experienced between 1 and 9 events.

19 Median HbA1c is reported in **Figure 3**. Overall median HbA1c fell from 64 mmol/mol (IQ range: 55 to 75) at time of transplant, to 51 mmol/mol (IQ range: 42 to 58) at one year post-transplant. The median HbA1c at three years post-transplant was 54 (IQ range: 48 to 63). Data were available to calculate the reduction in HbA1c in 82 cases and in 71 patients (87%) a reduction in HbA1c was reported at one year.

20 Fifteen patients, 15%, had HbA1c less than 53 mmol/mol at time of transplant and 46 patients, 56%, had HbA1c less than 53 mmol/mol at one-year post transplant. Of the 42 patients with HbA1c recorded at three years post-transplant, 17 (40%) had an HbA1c less than 53 mmol/mol.

21 **Figure 4** shows the median insulin dose at transplant and 3 months, 6 months, one year, two and three years post-transplant. The median insulin dose fell from 0.49 units/kg (IQ range: 0.33 to 0.60) at time of transplant to 0.27 units/kg (IQ range: 0.15 to 0.40) at 3 months post-transplant. This reduction in dose was maintained at one year, two years and three years post-transplant (0.25 units/kg, 0.27 units/kg and 0.27 units/kg respectively). Of 71 patients where information was available, a reduction in insulin dose at one year was reported for 64 (70%) patients.

SUMMARY

22 The number of islet transplants in 2016 and patients on the islet transplant list at the end of the year have fallen slightly on the previous year. Graft survival, reduction in rate of severe hypoglycaemic events, reduction in HbA1c and reduction in insulin dose at one year, two years and three years post routine transplant have been reported.

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Figure 1 **One-year graft survival following routine islet transplantation performed in the UK between 1 April 2010 and 31 December 2015**

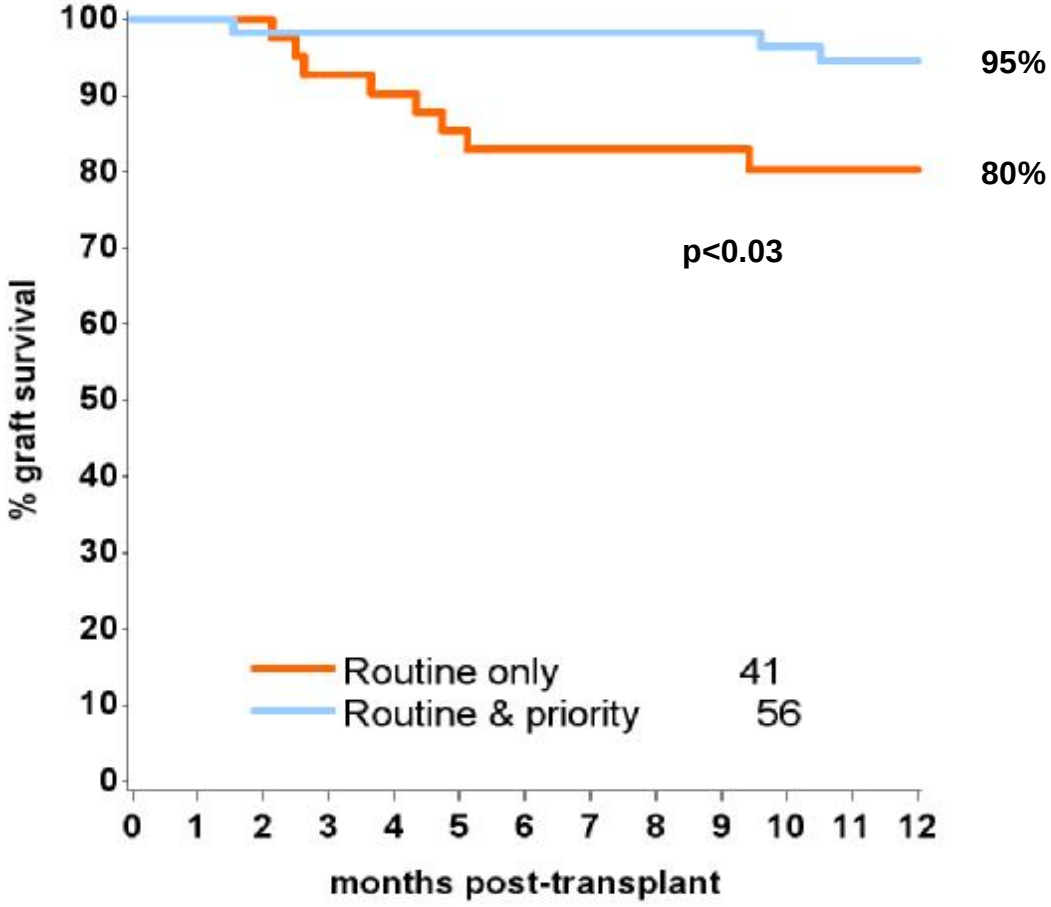

Figure 2 **Reduction in severe hypoglycaemic events three years post-transplant, 1 April 2010 – 31 December 2015**

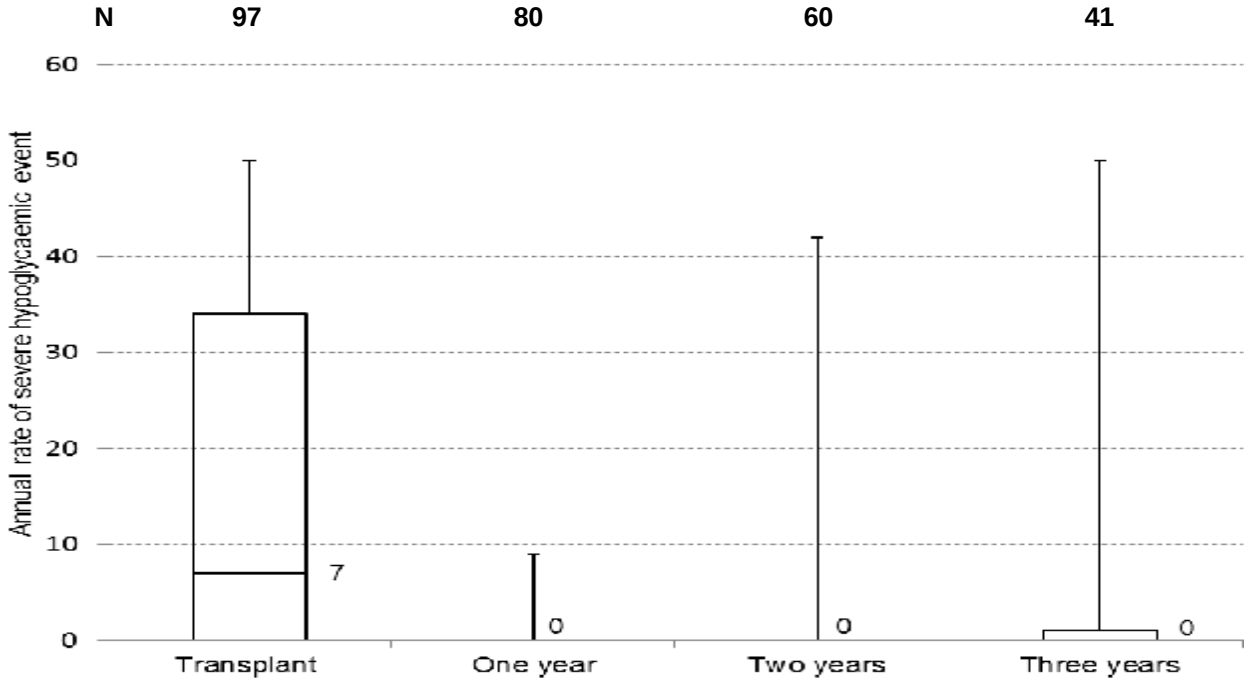

Figure 3 **Reduction in HbA1C three years post-transplant, 1 April 2010 – 31 December 2015**

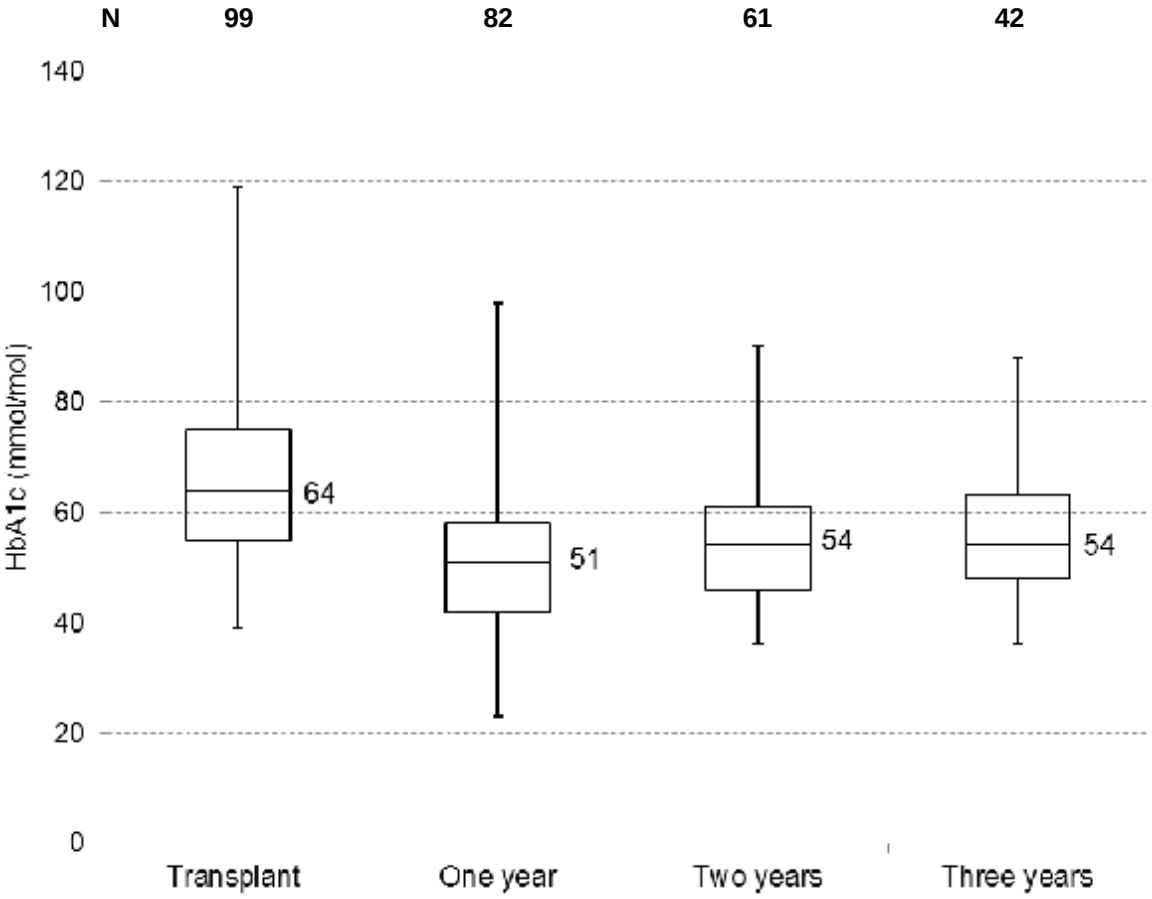

Figure 4 **Insulin dose three-years post-transplant, 1 April 2010 – 31 December 2015**