ANZIPTR Report 2018

Australia and New Zealand Islet and Pancreas Transplant Registry data 1984-2017

This report is a compilation of data provided by Pancreas transplant units in Australia and New Zealand. The registry is funded in part by a grant from the Commonwealth Department of Health and Ageing www.anziptr.org

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This report is produced and edited by: Professor Angela Webster, James Hedley and Associate Professor Patrick Kelly.

Chapters 1-3 are authored by: Angela Webster, Paul Robertson, Tia Mark, James Hedley, Patrick Kelly

Chapter 4 is authored by: Patricia Anderson, Natasha Rogers, James Hedley, Angela Webster

Chapter 5 is authored by: Toby Coates, James Hedley, Angela Webster

Chapter 6 is authored by: James Hedley, Patrick Kelly, Angela Webster

We thank all contributors who have made the registry what it is and whose work has made this report possible.

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ANZIPTR staff

Prof Jeremy Chapman	Westmead Medical Director
Prof Angela Webster	Registry Executive Officer
Abhijit Patekar	Data Analyst
Paul Robertson	Transplant Co-ordinator
Julie McKelvey	Registry Clerk
A/Prof Patrick Kelly	Biostatistics Consultant, The University of Sydney
James Hedley	Data Manager and Biostatistician

Contact the ANZIPTR

Inquiries or comments should be directed to ANZIPTR:

Australia and New Zealand Islet and Pancreas Transplant Unit

Westmead NSW 2145

Phone: +61 2 9845 6962 Fax: +61 2 9633 9351

Email: info@anziptr.org; Abhijit.Patekar@health.nsw.gov.au

Governance structure

This report is a compilation of data provided by the three current solid-organ Pancreas transplant units in Australia and New Zealand: Auckland Renal Transplant Group, New Zealand; National Pancreas Transplant Unit Monash Medical Centre, Victoria; and National Pancreas Transplant Unit, Westmead Hospital, NSW, and the three Islet transplanting units in Australia: Westmead Hospital (New South Wales), St. Vincent's Hospital Melbourne (Victoria), and Royal Adelaide Hospital (South Australia). The ANZIPTR registry is funded in part by a grant from the Commonwealth Department of Health and Ageing.

Data release guidelines

The registry can provide de-identified data for free to Transplant Physicians, Transplant Units, and Government Departments. Release of data for academic or clinical research projects is provisional on an agreed project plan and proof of ethical oversight. The registry will not provide any personally identifiable data.

The clinical data provided contains potentially sensitive information and should be used only within agreed guidelines. If data are further published elsewhere ANZIPTR permission is necessary prior to submission for publication, and ANZIPTR should be identified as the source of the data. If data provided by ANZIPTR is the primary source of data, then a copy of publication should be provided to ANZIPTR.

Data provided by ANZIPTR should be utilised by requesting parties only, further data sharing with other parties or projects is not permitted without prior approval from ANZIPTR. The data supplied will be in accordance with ANZIPTR data specifications. Please see www.anziptr.org for our data dictionary.

Participating Centres

Pancreas solid-organ centres

Auckland Renal Transplant Group

Dr Helen Pilmore

Prof Stephen Munn

Monash Medical Centre

Prof Peter Kerr	Director of Nephrology
Prof John Kanellis	Director of Transplantation
A/Prof Bill Mulley	Physician
Mr Alan Saunder	Director of Surgery
Mr Roger Bell	Surgeon
Mr Ming Yii	Surgeon
Miss Nancy Suh	Surgeon
Mr Stephen Thwaites	Surgeon
Mr Michael Wu	Surgeon
Ms Tia Mark	Transplant Coordinator

Westmead Hospital

Prof Henry Pleass	Director of Transplant Surgery
Prof Philip O'Connell	Director of Transplant Medicine
Prof Jeremy Chapman	Medical Director
Dr Brian Nankivell	Physician
Prof Angela Webster	Physician
A/Prof Germaine Wong	Physician
Dr Natasha Rogers	Physician
Dr Brendan Ryan	Surgeon
Dr Lawrence Yuen	Surgeon
Prof Richard Allen	Surgeon
Dr Jane Holmes-Walker	Endocrinologist
Ms Kathy Kable	Transplant Nurse Practitioner
Mr Paul Robertson	Transplant Co-ordinator

Prof Wayne Hawthorne	Director Transplant Laboratories
Mr Abhijit Patekar	Data Manager

Islet centres

Westmead Islet Centre (Sydney, New South Wales)

Professor Phillip O'Connell	Director of Transplant Medicine and the Clinical Islet Transplant Program
Dr Natasha Rogers	Staff Specialist
Prof Wayne Hawthorne	Director of the National Pancreas and Islet Transplant Laboratories
Ms Patricia Anderson	Islet Transplant Co-ordinator

St. Vincent's Islet Centre (Melbourne, Victoria)

Prof Thomas Kay	Director of St. Vincent's Institute
Prof Richard MacIsaac	Director of Endocrinology
A/Prof David Goodman	Director of Kidney and Islet Transplantation
A/Prof Glenn Ward	Director of Diabetes Services
Dr Thomas Loudovaris	Director of the Islet Isolation facility
Ms Kathy Howe	Islet Transplant Co-ordinator

Royal Adelaide Hospital Islet Centre (Adelaide, South Australia)

Prof Toby Coates	Director of kidney and islet transplantation
Prof David Torpy	Endocrinologist
Dr Anthony Roberts	Endocrinologist
Mr Chris Russell	Surgeon
Mr Santosh Olakkengil	Surgeon
Mr Chris Drogemuller	Principal scientist
Ms Toni Radford	Islet transplant co-ordinator

Analysis and Methods

The aim of this report is to record all pancreas transplant activity in Australia and New Zealand. Data included in this report was extracted from RISC (Renal Information System

Catalogue) on the 6th February 2018, for all people transplanted up to the end of 2017. Pancreas waiting list data was extracted from REDCap on the 15th February 2018, and data for the islets waiting list, donors, and recipients was extracted from FileMaker on the 6th February 2018. Please note new data is added to the registry regularly, and corrections are made where previous data are missing or where errors are discovered. This year's report continues with the new format and contents started in 2015. During 2017 we were able to correct many of the missing and problematic data we identified during 2016. We have also expanded chapter 4 Islet transplantation substantially and added two new chapters (chapter 5 on auto-islet transplant activity and chapter 6 on data quality).

Kaplan-Meier survival curves were used to illustrate the survival distributions, and these were generated using Stata software version 14 (StataCorp, College Station, TX USA). Transplant survival is analysed and presented both including and excluding death with a functioning transplant. For patients receiving a second transplant, in calculating mortality, time was measured from time of first transplant.

Definitions

Pancreas solid organ

A functioning pancreas transplant is defined as a recipient free of exogenous insulin dependence; thus a pancreas transplant failure is declared when either a pancreatectomy is performed, or when the recipient returns to permanent insulin therapy. Kidney transplants are defined as functioning if recipients are dialysis free. All causes of death are included in the mortality analyses.

Islets

An islet transplant is the infusion of islet cells that have been isolated from a donor pancreas into a recipient with poorly controlled type 1 diabetes who has recurrent severe hypoglycaemia and hypoglycaemia unawareness. In the case of an islet auto- transplant, the recipient is also the donor. Auto-islet transplantation is the re-infusion of islet cells from isolated from the recipient's own pancreas after the pancreas has been removed. This procedure is done to eradicate the severe pain of chronic or hereditary pancreatitis, to better control blood glucose after the pancreas is removed. In this report "islet transplant" refers to islet cell infusion from a cadaveric donor only; when discussing auto-islet transplantation "auto-islet" is always specified.

A functioning islet transplant is defined as stable blood glucose levels, cessation of severe hypoglycaemia, positive blood C-Peptide levels and reduction in insulin usage. Insulin independence may or may not be achieved and is not the aim of the procedure. Insulin independence is defined as being free from insulin use for 14 or more consecutive days. Note that the definition used here is different from the International Islet Registry, which defines insulin independence as less than 7 units of insulin per day.

Glossary

SPK	Simultaneous Kidney Pancreas Transplant
PTA	Pancreas Transplant Alone
PAK	Pancreas after Kidney Transplant
ITA	Islet Transplant Alone
PLK	Pancreas Liver Kidney
PLI	Pancreas Liver Intestine
DBD	Donor after Brain Death
DCD	Donor after Circulatory Death
CMV	Cytomegalovirus
EBV	Epstein-Barr Virus
IgG	Immunoglobulin G antibody
IEQ	Islet Equivalent Units
GMP	Good Manufacturing Procedures
TGA	Therapeutic Goods Administration (Australia)
HbA1c	Glycosylated haemoglobin A1c
SF36	36 Item Short Form Health Survey
SD	Standard Deviation
IQR	Interquartile Range
SVHM	St. Vincent's Hospital Melbourne
SVI	St. Vincent's Institute
NSW	New South Wales
VIC	Victoria
QLD	Queensland
SA	South Australia
WA	Western Australia
TAS	Tasmania
ACT	Australian Capital Territory
NT	Northern Territory
NZ	New Zealand

Synopsis

A total of 809 solid organ pancreas transplants have been performed in Australia and New Zealand (ANZ), in 790 individuals from 1984-2017 (excluding islet transplants).

In 2017, 52 people received a pancreas transplant, by centre this was; Auckland (4); Monash (17); Westmead (31). In 2017, 51 transplants were SPK while 1 was PAK and none were PTA.

From 2002-2017, 104 Islet transplants have been performed in 62 patients (excluding auto-islets).

Accessing report data

In 2015 ANZIPTR developed its own website: www.anziptr.org which describes the registry structure and function, outlines the procedure for data requests, and provides a download area for past reports. Since 2017, a slide set of key registry data tables and plots is available for download, to complement the ANZIPTR report.

The ANZIPTR welcomes suggestions for improvement or specific analyses you would like to see in the next annual report.

Chapter 1: Waiting List

Authors: Angela Webster, Paul Robertson, Tia Mark, James Hedley, Patrick Kelly

Overview of waiting list activity

Definitions

Patients join the waiting list on the date they are referred to the transplanting centre; however this may occur some time before their kidneys fail. Patients are therefore classified as “under consideration” until they medically require a kidney pancreas transplant. Once they require a kidney pancreas transplant they are classified as “active” on the list while they remain medically fit. The “under consideration” classification also captures people recently referred to the transplant centre, who are still undergoing assessment about their medical fitness for pancreas transplant. People referred to a transplanting centre when they are already on dialysis, become “active” on the list as soon as they are accepted as medically fit. People referred to a transplanting centre when their kidneys still function, become active once their kidney disease progresses to such a level that dialysis is planned in the near future. Once active on the waiting list, patients are transplanted in order of their waiting time, by blood group.

Patient waiting list flow

The patient waiting list activity in the last three years for Australia (Westmead and Monash Units) and New Zealand are shown in Tables 1.1 and 1.2 respectively. In Australia, although the number of transplants has increased over the last three years, the number of patients on the active waiting list has continued to increase.

Table 1.1: Waiting list activity in Australia for the last three years

Activity	Patients (n)		
	2015	***2016***	***2017***
On active list at beginning of year	59	40	60
Added to active list during the year	42	123	52
Removed from active list during year	12	24	4
Pancreas transplants to patients on waiting list [1]	45	51	50
Kidney only transplants	0	3	2
Transplants performed outside Australia/New Zealand	0	0	0
Died while active on list	4	4	1
On active waiting list at the end of year	40	81	57
Died within 12 months of removal from list	0	1	9
Under consideration but not active on list	97	112	198
Referred but declined for pancreas transplantation	12	19	39

[1] Excluding kidney only transplants and transplants performed outside Australia/New Zealand

Table 1.2: Waiting list activity in New Zealand for the last three years

Activity	Patients (n)		
	2015	***2016***	***2017***
On active list at beginning of year	5	7	4
Added to active list during the year	-	-	7
Removed from active list during year	-	-	1
Pancreas transplants to patients on waiting list [1]	0	4	4
Kidney only transplants	-	-	0
Transplants performed outside Australia/New Zealand	-	-	0
Died while active on list	-	-	1
On active waiting list at the end of year	-	-	4
Died within 12 months of removal from list	-	-	1
Under consideration but not active on list	3	4	3
Referred but declined for pancreas transplantation	-	-	0

Fields marked "-" were not captured prior to 2017

[1] Excluding kidney only transplants and transplants performed outside Australia/New Zealand

Distribution of active patients by state

Figure 1.1, Table 1.3, and Table 1.4 show the state of residence for people active on the pancreas waiting list, by the pancreas transplanting centre they were referred to (Australia only).

Figure 1.1: Distribution of people active on the waiting list by state of residence, as of December 2017

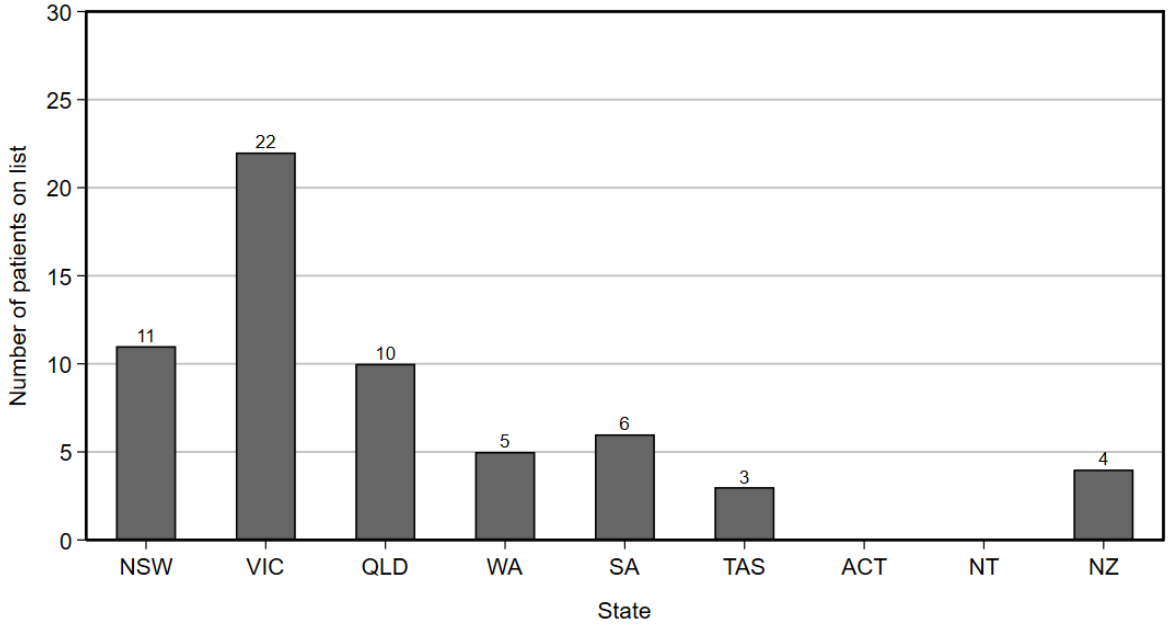


Table 1.3: Patient state of residence for people active on the list at Westmead national pancreas transplant unit (NSW), December 2017

State of residence	Patients, n (row %)								
	NSW	***VIC***	***QLD***	***SA***	***WA***	***TAS***	***ACT***	***NT***	***Total***
2017	11 (41)	0 (0)	10 (37)	1 (4)	5 (19)	0 (0)	0 (0)	0 (0)	27 (100)
2016	21 (50)	0 (0)	12 (29)	1 (2)	5 (12)	0 (0)	2 (5)	1 (2)	42 (100)
2015	16 (39)	1 (2)	13 (32)	2 (5)	5 (12)	0 (0)	3 (7)	1 (2)	41 (100)

Table 1.4: Patient state of residence for people active on the list at Monash pancreas transplant unit (VIC), December 2017

State of residence	Patients, n (row %)								
	NSW	***VIC***	***QLD***	***SA***	***WA***	***TAS***	***ACT***	***NT***	***Total***
2017	0 (0)	*22 (73)*	0 (0)	*5 (17)*	0 (0)	*3 (10)*	0 (0)	0 (0)	*30 (100)*
2016	0 (0)	29 (74)	0 (0)	6 (15)	0 (0)	4 (10)	0 (0)	0 (0)	39 (100)
2015	0 (0)	32 (70)	0 (0)	12 (26)	0 (0)	2 (4)	0 (0)	0 (0)	46 (100)

Table 1.5 and Table 1.6 show the state of residence for people who are under consideration together with people who are active on the pancreas waiting list, by the pancreas transplanting centre they were referred to, in Australia. For New Zealand data, there is no breakdown beyond that seen in Table 1.2.

Table 1.5: State of residence for people under consideration and for people active on the list at Westmead national pancreas transplant unit (NSW), December 2017

State of residence	Patients, n (row %)								
	NSW	***VIC***	***QLD***	***SA***	***WA***	***TAS***	***ACT***	***NT***	***Total***
2017	59 (40)	1 (1)	39 (26)	9 (6)	39 (26)	1 (1)	0 (0)	0 (0)	*148 (100)*
2016	*38 (37)*	0 (0)	*30 (29)*	*4 (4)*	*23 (22)*	0 (0)	6 (6)	3 (3)	104 (100)
2015	38 (35)	1 (1)	28 (26)	8 (7)	26 (24)	0 (0)	5 (5)	3 (3)	109 (100)

Table 1.6: State of residence for people under consideration and for people active on the list at Monash pancreas transplant unit (VIC), December 2017

State of residence	Patients, n (row %)								
	NSW	***VIC***	***QLD***	***SA***	***WA***	***TAS***	***ACT***	***NT***	***Total***
2017	*1 (1)*	*79 (75)*	1 (1)	*15 (14)*	*0 (0)*	*8 (8)*	*0 (0)*	*1 (1)*	*105 (100)*
2016	0 (0)	57 (76)	1 (1)	10 (13)	0 (0)	7 (9)	0 (0)	0 (0)	75 (100)
2015	0 (0)	47 (65)	0 (0)	18 (25)	0 (0)	7 (10)	0 (0)	0 (0)	72 (100)

New referrals received over time

Tables 1.7, 1.8 and 1.9 show the distribution of new referrals received by the transplanting units over time.

Table 1.7: New referrals received by Westmead national pancreas unit (NSW)

State of residence	Patients, n (%)								
	NSW	***VIC***	***QLD***	***SA***	***WA***	***TAS***	***ACT***	***NT***	***Total***
2017	*16 (67)*	0 (0)	*8 (33)*	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	*24 (100)*
2016	24 (32)	0 (0)	23 (31)	4 (5)	16 (22)	0 (0)	5 (7)	2 (3)	74 (100)
2015	22 (38)	0 (0)	16 (28)	3 (5)	11 (19)	0 (0)	4 (7)	2 (3)	58 (100)
2014	25 (45)	1 (2)	12 (21)	4 (7)	9 (16)	0 (0)	2 (4)	3 (5)	56 (100)
2013	16 (34)	0 (0)	16 (34)	4 (9)	9 (19)	0 (0)	1 (2)	1 (2)	47 (100)
2012	14 (28)	0 (0)	13 (26)	6 (12)	12 (24)	0 (0)	3 (6)	2 (4)	50 (100)

Table 1.8: New referrals received by Monash pancreas transplant unit (VIC)

State of residence	Patients, n (%)								
	NSW	***VIC***	***QLD***	***SA***	***WA***	***TAS***	***ACT***	***NT***	***Total***
2017	0 (0)	42 (84)	0 (0)	6 (12)	0 (0)	1 (2)	0 (0)	1 (2)	50 (100)
2016	0 (0)	23 (64)	0 (0)	6 (17)	0 (0)	7 (19)	0 (0)	0 (0)	36 (100)
2015	0 (0)	18 (62)	0 (0)	9 (31)	0 (0)	2 (7)	0 (0)	0 (0)	29 (100)
2014	0 (0)	38 (79)	0 (0)	6 (13)	0 (0)	4 (8)	0 (0)	0 (0)	48 (100)
2013	0 (0)	30 (79)	0 (0)	5 (13)	0 (0)	3 (8)	0 (0)	0 (0)	38 (100)
2012	0 (0)	26 (81)	0 (0)	1 (3)	0 (0)	5 (16)	0 (0)	0 (0)	32 (100)

Table 1.9: New referrals received by Auckland national pancreas transplant unit (NZ)

Year	2017	2016	2015	2014	2013	2012
Referrals	3	7	0	9	4	5+

Patient characteristics for those active on the list in 2017

The following figures illustrate the distribution of other characteristics of those active on the waiting list in 2017, including the distribution of blood groups and patient ages.

Figure 1.2: Distribution of people active on the list by their blood group, at December 2017

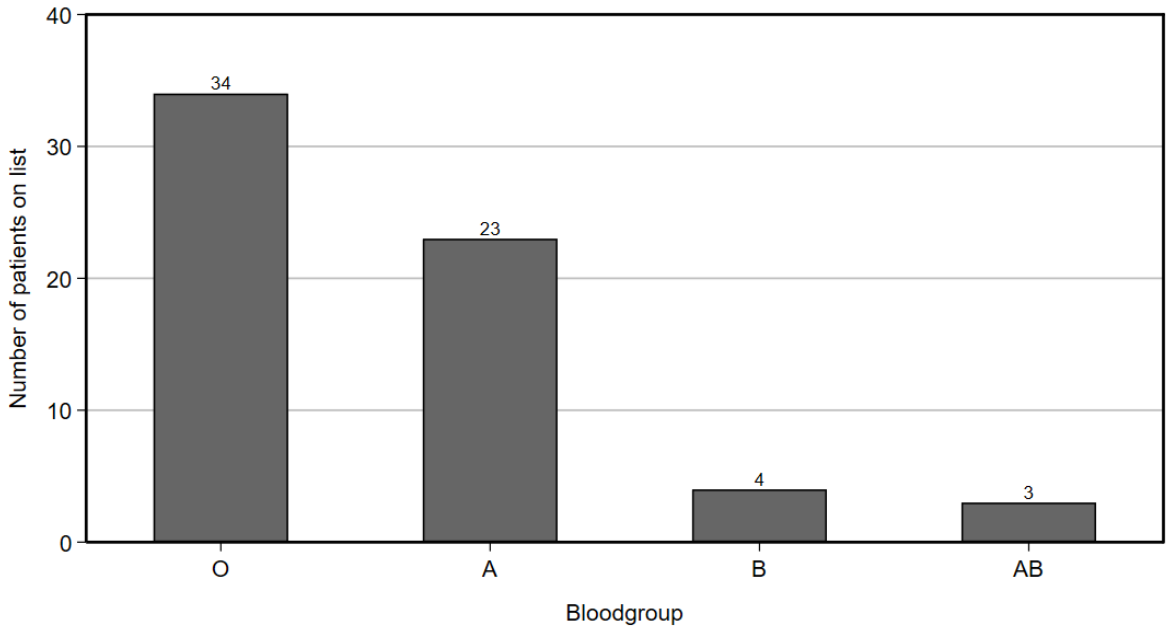
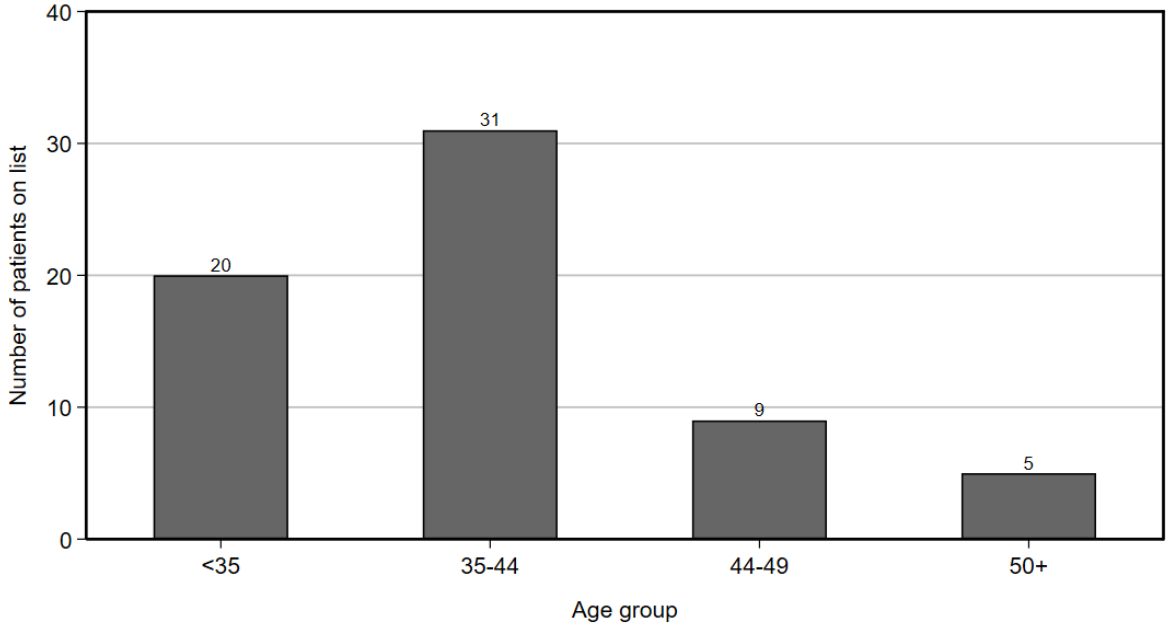


Figure 1.3: Distribution of people active on the list by their age, at December 2017



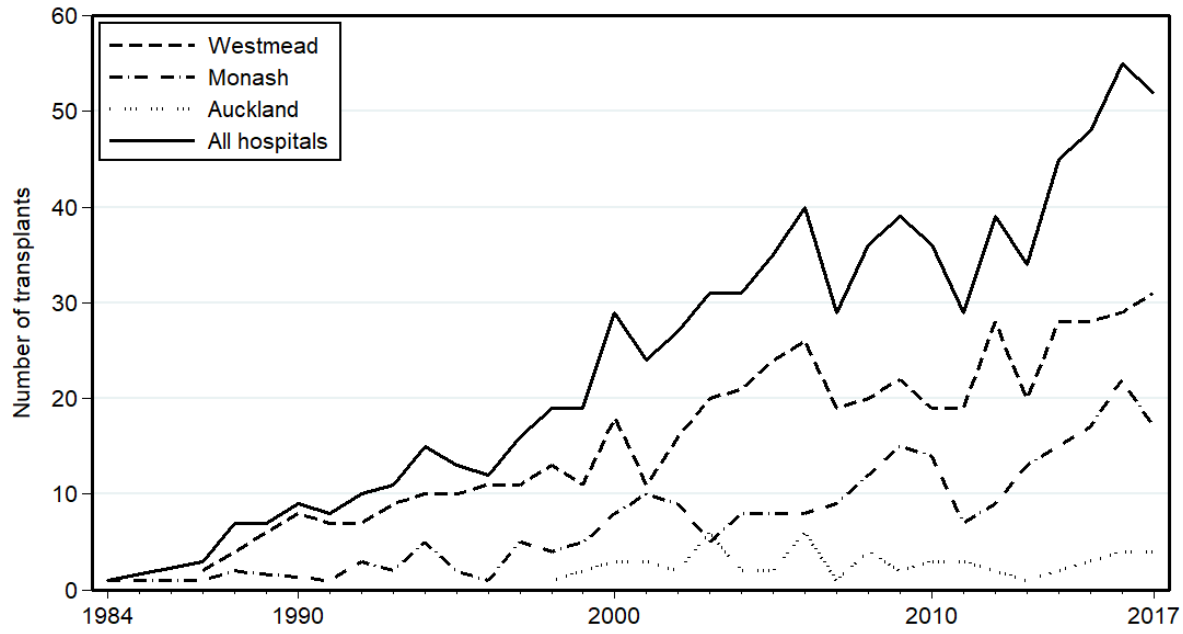
Chapter 2: Pancreas transplant recipients

Authors: Angela Webster, Paul Robertson, Tia Mark, James Hedley, Patrick Kelly

Pancreas transplant incidence

A total of 809 solid organ pancreas transplants have been performed in Australia and New Zealand (ANZ) from 1984-2017. Transplants have been performed in Westmead (511), Monash (238), Auckland (56). There have also been multi-organ transplants including pancreas at Royal Prince Alfred (1), Royal Melbourne Hospital (1), Queen Elizabeth Hospital (1), and Prince Henry (1). Figure 2.1 shows pancreas transplants over time. The number of transplants has substantially increased in last decade compared to previous years.

Figure 2.1: Incidence of pancreas transplants over time, 1984-2017.



Note: There have been four pancreas transplants performed in Australia, which were not conducted by either Westmead or Monash. These occurred in 1988, 1989, 1990 and 2005.

In 2017, 52 people received a pancreas transplant, by centre this was; Auckland (4); Monash (17); Westmead (31). The number of transplants in 2017 decreased by 5% compared to 2016.

Not all pancreas transplant operations are undertaken with the same organs. Simultaneous pancreas-kidney transplant (SPK) is the most common operation, representing 99% of all pancreas transplants in Australia and New Zealand. From 52 transplants performed in 2017, 51 were SPK and 1 was Pancreas after kidney (PAK), while none were Pancreas transplant alone (PTA). PAK operations are done for type 1 diabetic people who either had a first kidney transplant without a pancreas (most commonly from a living donor relative) and subsequently opt for a pancreas, or for people who underwent an SPK and have good kidney transplant function, but had a pancreas transplant failure, so need a further pancreas transplant. Pancreas transplant alone (PTA) is a less common operation and occurs very rarely. On rarer occasions, a multi-organ transplant is undertaken which includes a pancreas transplant. There was one simultaneous Pancreas, Liver plus Kidney transplant which was performed in 2005, one Liver, Pancreas plus Intestine transplant in 2012, and one Liver plus Pancreas transplant in 2016. The distribution of operation types is shown in Figure 2.2, and the number of transplants by operation type is shown in Table 2.1.

Figure 2.2: Pancreas transplants by type over time, Australia and New Zealand

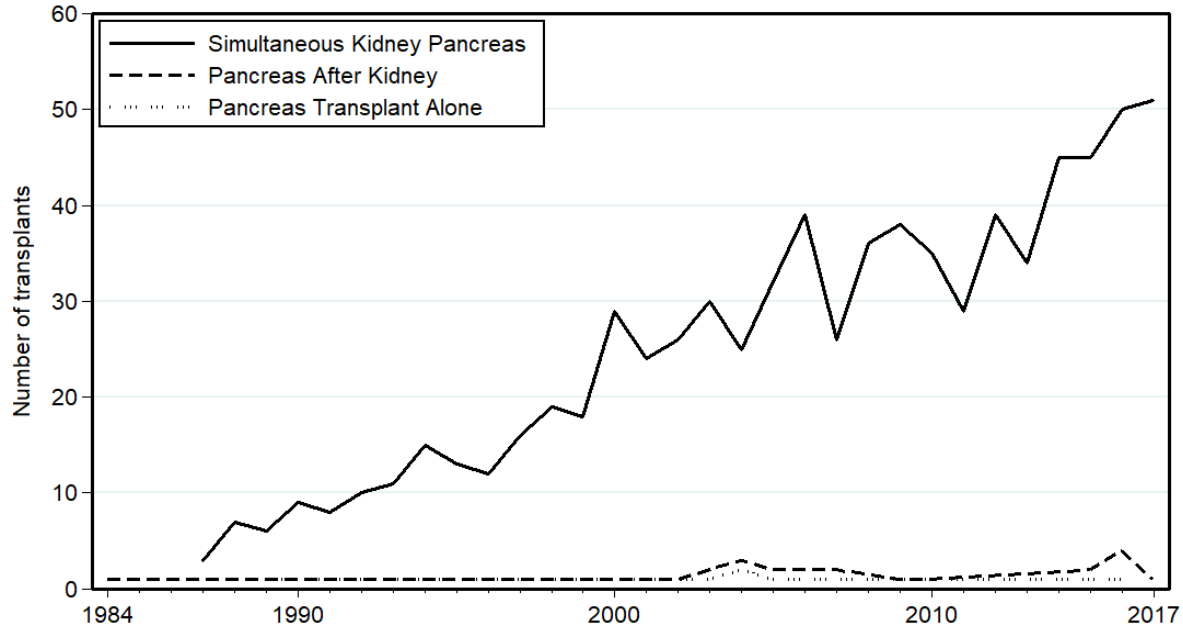


Table 2.1: Pancreas transplant operations by centre, over time

Year	Hospital and transplant type, n (%)														Total
	Westmead						*Monash*						New Zealand		
	SPK		*PAK*		*PTA*		*SPK*		*PAK*		*PTA*		*All*		
2017	31	(59)	0	(0)	0	(0)	16	(30)	1	(1)	0	(0)	4	(7)	52
2016	26	(47)	3	(5)	0	(0)	20	(36)	1	(1)	1	(1)	4	(7)	55
2015	27	(56)	1	(2)	0	(0)	16	(33)	1	(2)	0	(0)	3	(6)	48
2014	28	(62)	0	(0)	0	(0)	15	(33)	0	(0)	0	(0)	2	(4)	45
2013	20	(58)	0	(0)	0	(0)	13	(38)	0	(0)	0	(0)	1	(2)	34
2012	28	(71)	0	(0)	0	(0)	9	(23)	0	(0)	0	(0)	2	(5)	39
2011	19	(65)	0	(0)	0	(0)	7	(24)	0	(0)	0	(0)	3	(10)	29
2010	19	(52)	0	(0)	0	(0)	14	(38)	0	(0)	0	(0)	3	(8)	36
2009	22	(56)	0	(0)	0	(0)	14	(35)	1	(2)	0	(0)	2	(5)	39
2008	20	(55)	0	(0)	0	(0)	12	(33)	0	(0)	0	(0)	4	(11)	36
2007	16	(55)	2	(6)	1	(3)	9	(31)	0	(0)	0	(0)	1	(3)	29
2006	25	(62)	0	(0)	1	(2)	8	(20)	0	(0)	0	(0)	6	(15)	40
2005	21	(60)	2	(5)	1	(2)	8	(22)	0	(0)	0	(0)	2	(5)	35
2004	15	(48)	3	(9)	2	(6)	8	(25)	0	(0)	0	(0)	2	(6)	31
2003	19	(61)	0	(0)	1	(3)	5	(16)	0	(0)	0	(0)	6	(19)	31
2002	15	(55)	1	(3)	0	(0)	9	(33)	0	(0)	0	(0)	2	(7)	27
2001	11	(45)	0	(0)	0	(0)	10	(41)	0	(0)	0	(0)	3	(12)	24
2000	18	(62)	0	(0)	0	(0)	8	(27)	0	(0)	0	(0)	3	(10)	29
1999	11	(57)	1	(5)	0	(0)	5	(26)	0	(0)	0	(0)	2	(10)	19
1998	14	(73)	0	(0)	0	(0)	4	(21)	0	(0)	0	(0)	1	(5)	19
1997	11	(68)	0	(0)	0	(0)	5	(31)	0	(0)	0	(0)	0	(0)	16
1996	11	(91)	0	(0)	0	(0)	1	(8)	0	(0)	0	(0)	0	(0)	12
1995	11	(84)	0	(0)	0	(0)	2	(15)	0	(0)	0	(0)	0	(0)	13
1994	10	(66)	0	(0)	0	(0)	5	(33)	0	(0)	0	(0)	0	(0)	15
1993	9	(81)	0	(0)	0	(0)	2	(18)	0	(0)	0	(0)	0	(0)	11
1992	7	(70)	0	(0)	0	(0)	3	(30)	0	(0)	0	(0)	0	(0)	10
1991	7	(87)	0	(0)	0	(0)	1	(12)	0	(0)	0	(0)	0	(0)	8
1990	8	(88)	0	(0)	0	(0)	0	(0)	0	(0)	0	(0)	0	(0)	9
1989	5	(71)	0	(0)	1	(14)	0	(0)	0	(0)	0	(0)	0	(0)	7
1988	4	(57)	0	(0)	0	(0)	2	(28)	0	(0)	0	(0)	0	(0)	7
1987	2	(66)	0	(0)	0	(0)	1	(33)	0	(0)	0	(0)	0	(0)	3
1986	0	(0)	0	(0)	0	(0)	0	(0)	0	(0)	0	(0)	0	(0)	0
1985	0	(0)	0	(0)	0	(0)	0	(0)	0	(0)	0	(0)	0	(0)	0
1984	0	(0)	0	(0)	0	(0)	0	(0)	1	(100)	0	(0)	0	(0)	1
Total	490	(60)	13	(1)	7	(<1)	232	(28)	5	(<1)	1	(<1)	56	(6)	809

SPK= simultaneous pancreas-kidney; PAK= pancreas after kidney; PTA= pancreas alone

The above table excludes the four transplants performed in Australia outside of Westmead and Monash. These occurred in 1988, 1989, 1990, and 2005.

Patients transplanted by state

The states of origin of the people receiving pancreas transplants are shown in the following tables by transplanting centre: Table 2.2 for Westmead and Table 2.3 for Monash. Numbers for New Zealand can be found in Table 2.1.

Table 2.2: Distribution of state of residence of people receiving pancreas transplants in Australia over time at Westmead pancreas transplant unit (NSW)

Year	State, n (row %)																
	NSW		VIC		QLD		SA		WA		TAS		ACT		NT		Total
2017	16	(51)	0	(0)	11	(35)	0	(0)	2	(6)	0	(0)	2	(6)	0	(0)	31
2016	12	(41)	0	(0)	10	(34)	2	(6)	5	(17)	0	(0)	0	(0)	0	(0)	29
2015	16	(57)	0	(0)	8	(28)	1	(3)	1	(3)	0	(0)	0	(0)	2	(7)	28
2014	13	(46)	0	(0)	11	(39)	1	(3)	2	(7)	0	(0)	0	(0)	1	(3)	28
2013	7	(35)	0	(0)	8	(40)	0	(0)	3	(15)	0	(0)	1	(5)	1	(5)	20
2012	13	(46)	1	(3)	9	(32)	3	(10)	2	(7)	0	(0)	0	(0)	0	(0)	28
Total	77	(46)	1	(<1)	57	(34)	7	(4)	15	(9)	0	(0)	3	(1)	4	(2)	164

Table 2.3: Distribution of state of residence of people receiving pancreas transplants in Australia over time at Monash pancreas transplant unit (VIC)

Year	State, n (row %)																
	NSW		VIC		QLD		SA		WA		TAS		ACT		NT		Total
2017	0	(0)	14	(82)	0	(0)	2	(11)	0	(0)	1	(5)	0	(0)	0	(0)	17
2016	0	(0)	15	(68)	0	(0)	6	(27)	0	(0)	1	(4)	0	(0)	0	(0)	22
2015	0	(0)	13	(76)	0	(0)	1	(5)	0	(0)	3	(17)	0	(0)	0	(0)	17
2014	0	(0)	12	(80)	0	(0)	2	(13)	0	(0)	1	(6)	0	(0)	0	(0)	15
2013	2	(15)	10	(76)	0	(0)	1	(7)	0	(0)	0	(0)	0	(0)	0	(0)	13
2012	0	(0)	3	(33)	1	(11)	2	(22)	0	(0)	3	(33)	0	(0)	0	(0)	9
Total	2	(2)	67	(72)	1	(1)	14	(15)	0	(0)	9	(9)	0	(0)	0	(0)	93

Demographics of new pancreas transplant recipients

The characteristics of pancreas transplant recipients in 2017 and in previous years are shown in Table 2.4. The primary diagnosis causing end stage kidney disease of recipients during 2017 and historically was type I diabetes. The number of diabetic recipients with other cause of end stage kidney failure was small. The number of type II diabetics accepted for pancreas transplantation was also small, and none were transplanted in 2017.

Table 2.4: Demographics and characteristics of pancreas transplant recipients

Patients, n (%)	2017		1984-2016		Total	
Age category						
Median (IQR)	39.9	(36.3, 45.0)	39.0	(33.3, 44.4)	39.0	(33.4, 44.4)
0-34	9	(17)	250	(33)	259	(32)
35-44	28	(53)	334	(44)	362	(44)
45-50	10	(19)	123	(16)	133	(16)
50+	5	(9)	50	(6)	55	(6)
Sex						
Female	19	(36)	353	(46)	372	(45)
Male	33	(63)	404	(53)	437	(54)
Cause of end stage kidney disease						
Diabetes Type 1	22	(42)	311	(41)	333	(41)
Diabetes Type 2	0	(0)	3	(<1)	3	(<1)
Other	2	(3)	7	(<1)	9	(1)
Uncertain diagnosis	28	(53)	436	(57)	464	(57)
Ethnicity						
Australian Aboriginal	0	(0)	2	(<1)	2	(<1)
Maori	0	(0)	5	(<1)	5	(<1)
Pacific islander	1	(1)	4	(<1)	5	(<1)
White	36	(69)	721	(95)	757	(93)
Indian	0	(0)	13	(1)	13	(1)
Arab	0	(0)	8	(1)	8	(<1)
Chinese	0	(0)	2	(<1)	2	(<1)
Asian	0	(0)	1	(<1)	1	(<1)
Unknown	15	(28)	1	(<1)	16	(1)
Blood group						
O	22	(42)	342	(45)	364	(44)
A	21	(40)	278	(36)	299	(36)
B	7	(13)	68	(8)	75	(9)
AB	2	(3)	33	(4)	35	(4)
Unknown	0	(0)	36	(4)	36	(4)
Total	52		757		809	

Ethnicity classified according to the Australian Bureau of Statistics standard classification, 2nd Edition;http://www.abs.gov.au/AUSSTATS/abs@.nsf/DetailsPage/1249.02011?OpenDocument

The type of pancreas transplants and the types of donors for transplants performed in 2017 is presented in Table 2.5, stratified by country and sex.

Table 2.5: Transplant and donor types in 2017 by country and sex

	Australia			New Zealand			Overall		
	Female	*Male*	*Total*	*Female*	*Male*	*Total*	*Female*	*Male*	*Total*
Pancreas alone	1	0	1	0	0	0	1	0	1
DBD	0	0	0	0	0	0	0	0	0
DCD	0	0	0	0	0	0	0	0	0
Unknown	1	0	1	0	0	0	1	0	1
SPK	14	33	47	4	0	4	18	33	51
DBD	13	33	46	0	0	0	13	33	46
DCD	1	0	1	0	0	0	1	0	1
Unknown	0	0	0	4	0	4	4	0	4

DBD, donor after brain death; DCD, donor after circulatory death; SPK, simultaneous pancreas-kidney

Balance of donor and recipient characteristics in 2017

Cross tabulations of donor and recipient blood group and gender for people transplanted in 2017 are displayed in Table 2.5 and Table 2.6. These distributions remain similar to previous years.

Table 2.6: Cross tabulation of recipient and donor blood groups for 2017

Recipient blood group	Donor blood group, n (row %)								Total
	O		*A*		*B*		*AB*		
O	21	(95)	0	(0)	0	(0)	0	(0)	22
A	1	(4)	17	(80)	0	(0)	0	(0)	21
B	0	(0)	0	(0)	7	(100)	0	(0)	7
AB	0	(0)	0	(0)	0	(0)	2	(100)	2
Total	22	(42)	17	(32)	7	(13)	2	(3)	52

Table 2.7: Cross tabulation of recipient and donor sex for 2017

Recipient sex	Donor sex, n (row %)				Total
	Female		*Male*		
Female	3	(15)	12	(63)	19
Male	14	(42)	19	(57)	33
Total	17	(32)	31	(59)	52

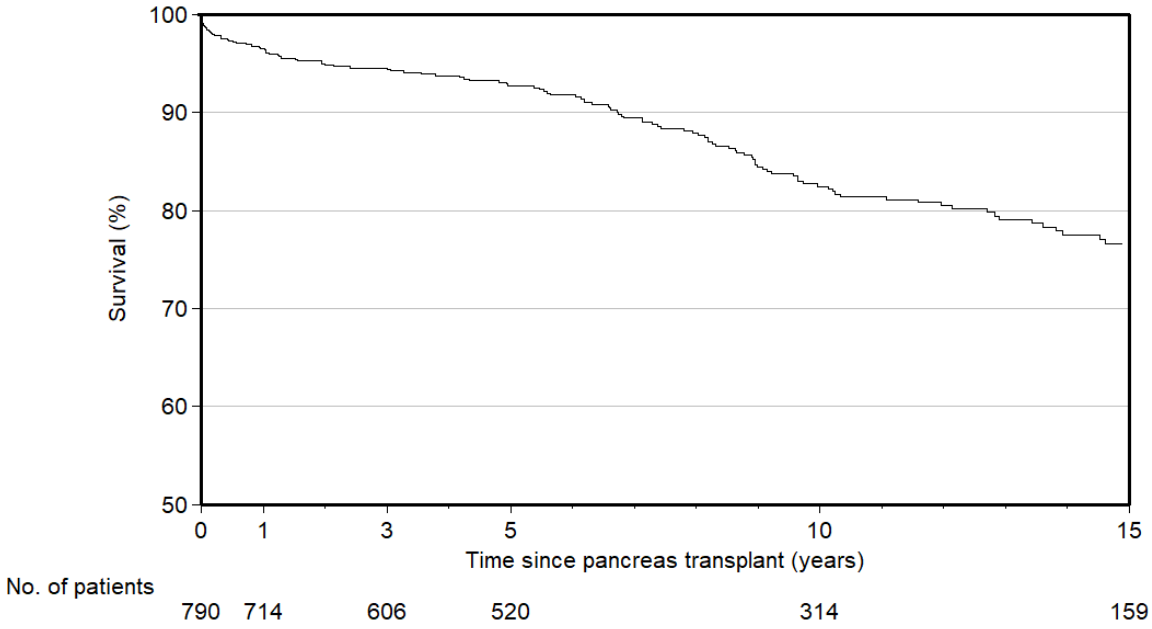
McNemar's test for difference p=0.8

Patient survival

Patient survival is calculated from the date of transplantation until death. Patients still alive at the end of the follow-up period are censored. For people who had more than one transplant, their survival is calculated from the date of their first transplant. For these analyses we had survival data for 790 patients, 19 of whom have received a second pancreas transplant, for a total of 809 pancreas transplants. Note that for the following survival plots survival proportion on the y-axes does not always start at zero; this is to better demonstrate some observed differences.

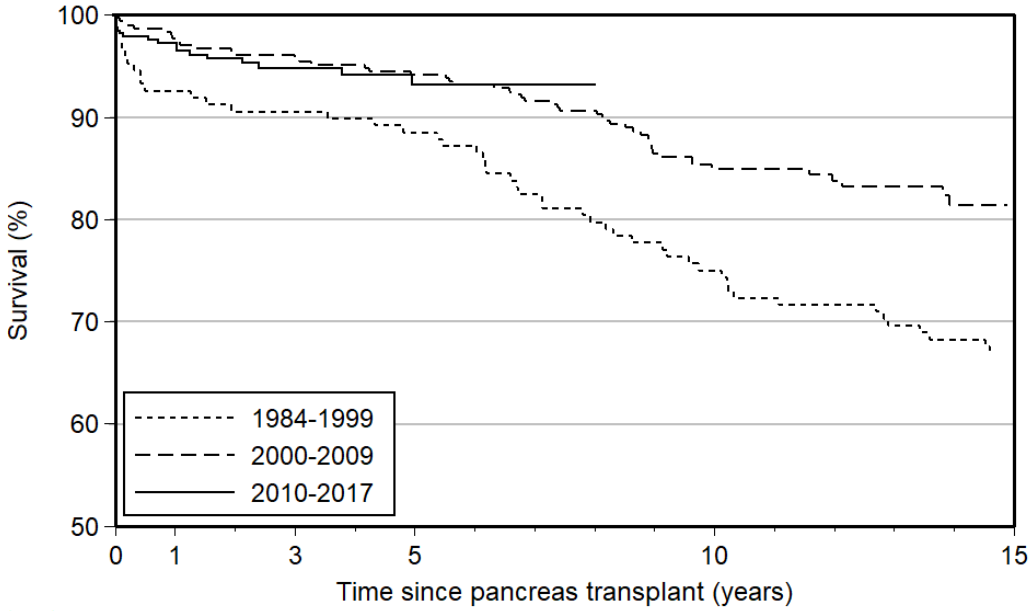
Figure 2.3 shows overall survival following pancreas transplant. There were 7,199 years of observation, and 141 people died in that time. Survival at 1 year was 96.5%, at 5 years 92.7%, at 10 years 82.5% and at 15 years 76.6%.

Figure 2.3: Patient survival following pancreas transplantation in Australia and New Zealand.



Patient survival by era of transplantation is shown in Figure 2.4. Survival has improved over time (p=0.002). Survival at 1 year for people transplanted before 2000 was 92.6%; in recent years this has risen to 97.2%. Survival at 5 years was 88.5% for those transplanted before 2000, where for those transplanted in 2010 or later, 5 year survival was 93.2%.

Figure 2.4: Patient survival by era of transplantation

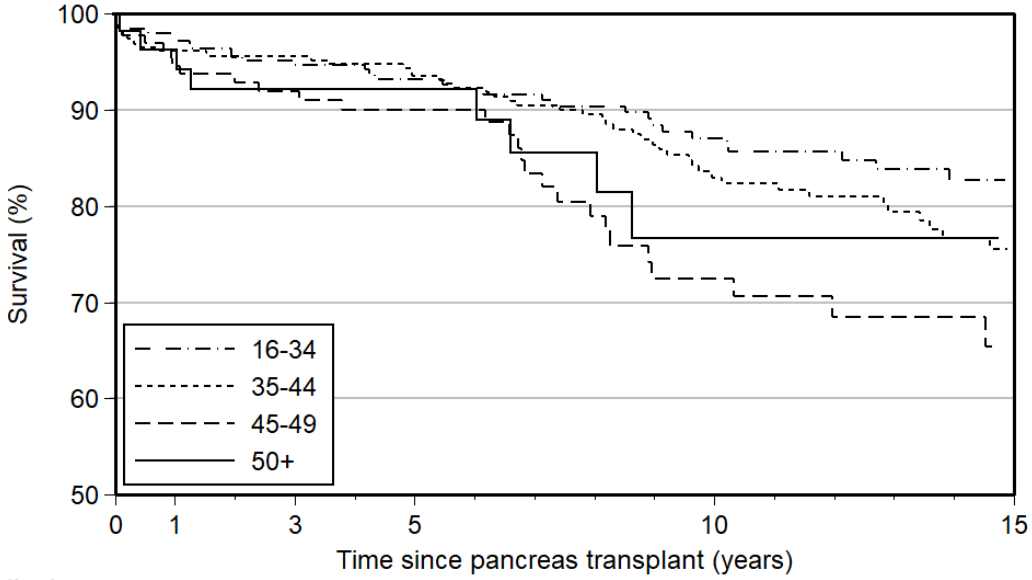


No. of patients

1984-1999	148	137	134	131	111	99
2000-2009	310	303	298	292	203	60
2010-2017	332	274	174	97	0	0

Patient survival by age at transplantation is shown in Figure 2.5. People that were older at the time of pancreas transplantation had poorer survival than those who were younger (p=0.005). Survival at 1 year for recipients aged <35 years was 98.0%, and for those aged 35-44 was 96.2%, whereas for those aged 45-49 was 94.6% and for those 50 or older was 96.3%. Five-year survival for those aged <35 years was 93.3%, and for those aged 35-44 was 93.6%, whereas for those aged 45-49 was 90.1% and for those 50 or older was 92.2%. The greater survival for the 50 years and older group suggests these recipients may be a more highly selected population.

Figure 2.5: Patient survival by age at transplantation



No. of patients

16-34	255	241	209	182	123	66
35-44	348	309	263	224	137	67
45-49	132	116	97	83	40	20
50+	55	48	37	31	14	6

Pancreas survival

Pancreas transplant survival was calculated from the time of transplant until the time of permanent return to insulin therapy or pancreatectomy. We calculated both pancreas failure including death with a functioning pancreas and pancreas failure censored for death with a functioning graft. For pancreas graft survival we included all pancreas transplants undertaken, including those who had received a pancreas transplant twice (19 patients). At the time of this report, we had survival records for 809 pancreas transplants.

Figure 2.6 shows pancreas survival censored for death. Over 6,821 years of observation, there were 162 pancreas graft failures (excluding people who died with a functioning transplant). Overall, 1-year pancreas graft survival was 87.3%, 5-year survival 82.6%, and 10-year survival 79.2%.

Figure 2.6: Pancreas transplant survival, excluding death with a functioning pancreas graft

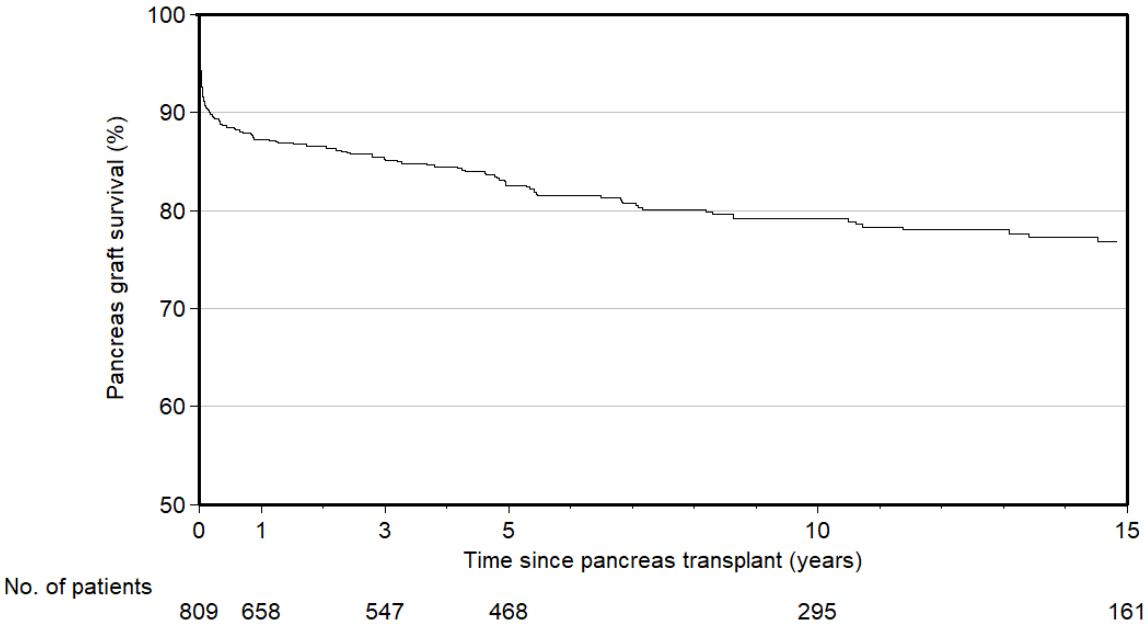
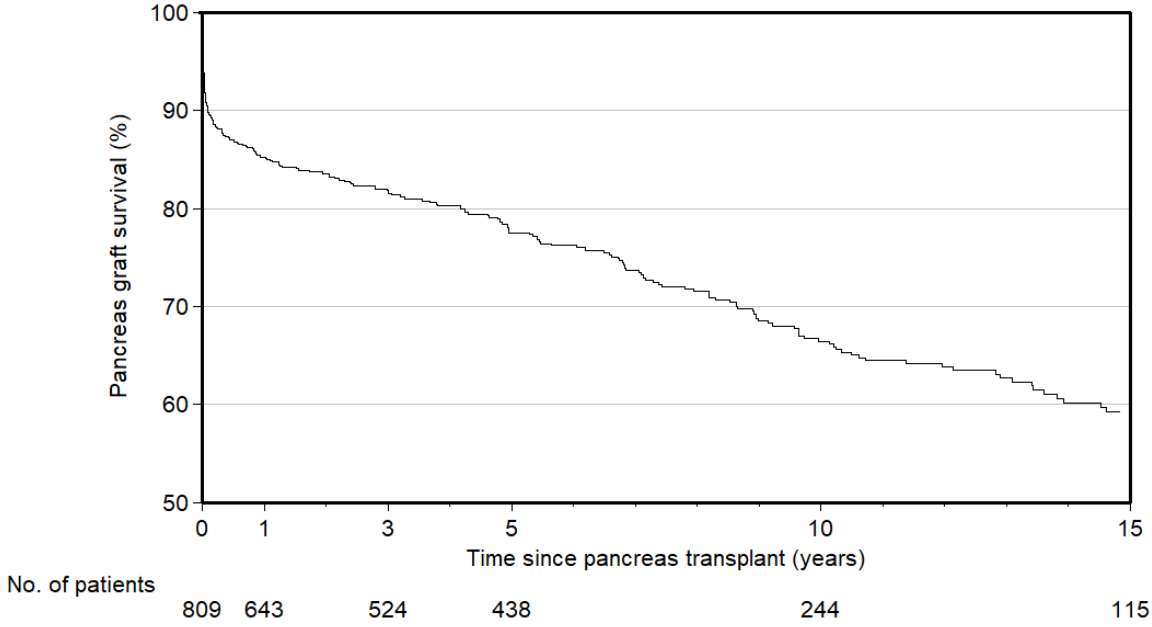


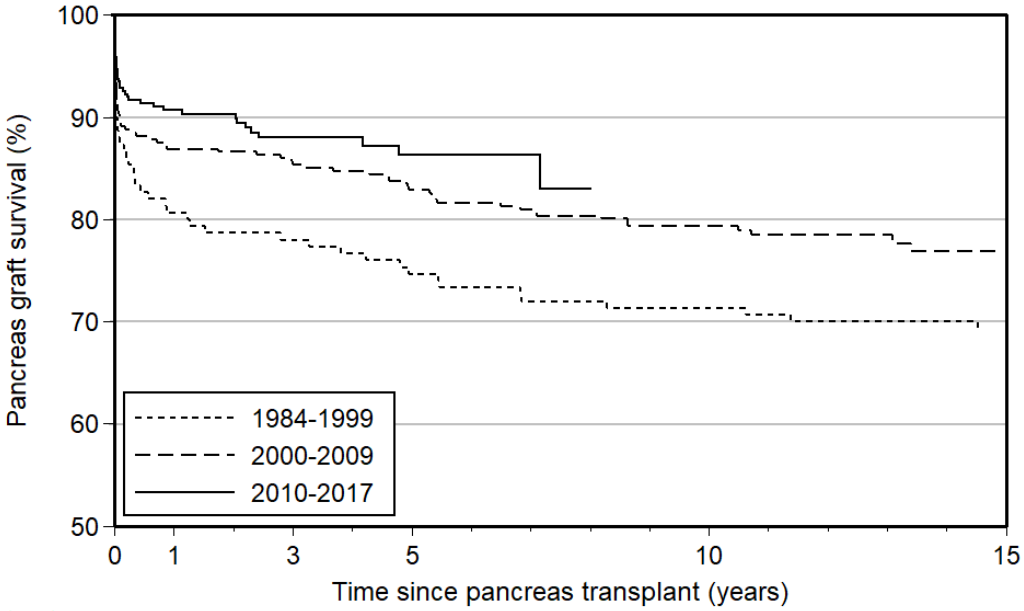
Figure 2.7 shows pancreas survival including death with a functioning pancreas. Over the same observation time there were 265 recipients who died with their pancreas still functioning. One, 5 and 10-year survival were 85.3%, 77.5% and 66.5% respectively.

Figure 2.7: Pancreas transplant survival, including death with a functioning pancreas graft.



Survival of pancreas transplants has changed over time, as shown in Figure 2.8. Survival improved markedly over time (p=0.02). For those transplanted prior to 2000, 1-year pancreas survival was 80.7%, and 5-year survival 74.7%. For those transplanted in 2010 or later, 1-year survival was 90.7% and 5-year survival 86.4%.

Figure 2.8: Pancreas transplant survival over time (censored for death)

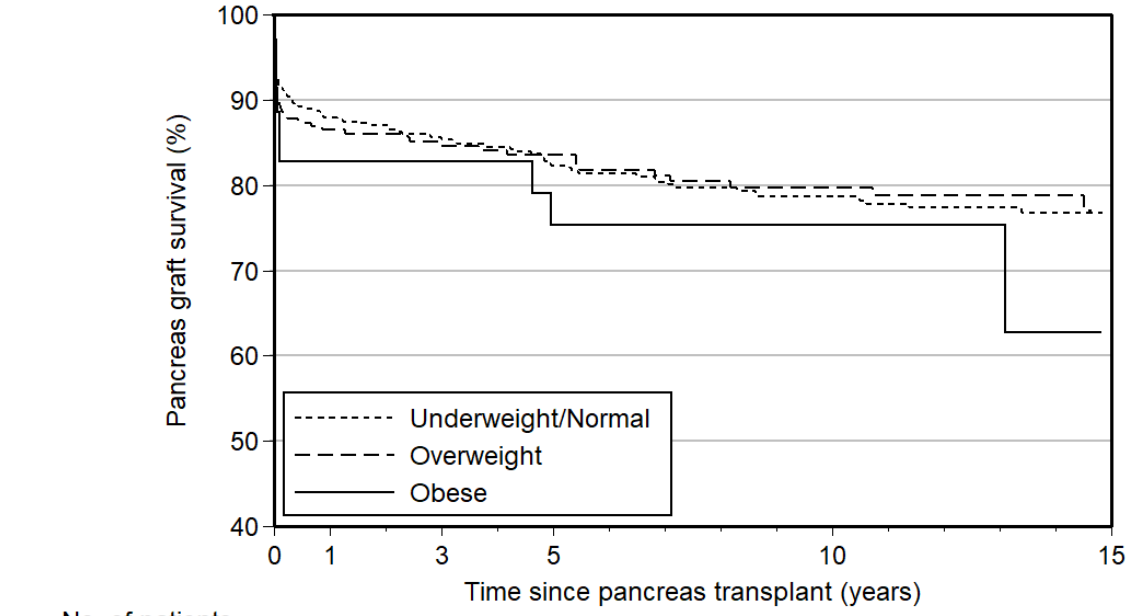


No. of patients

1984-1999	150	121	117	112	107	104
2000-2009	321	279	275	266	188	57
2010-2017	338	258	155	90	0	0

Pancreas survival by donor BMI is presented in Figure 2.9. Most donors (64%) were either underweight or normal (BMI <25). However, 31% were overweight (BMI 25-29) and 4% were obese (BMI 30+). While Figure 2.9 suggests separation of survival curves, there was no statistical association between donor BMI and pancreas survival (p=0.7). One-year pancreas survival was 87.9% for transplants where the donor was underweight/normal BMI, 86.5% for transplants where the donor was overweight, and 82.9% where the donor was obese.

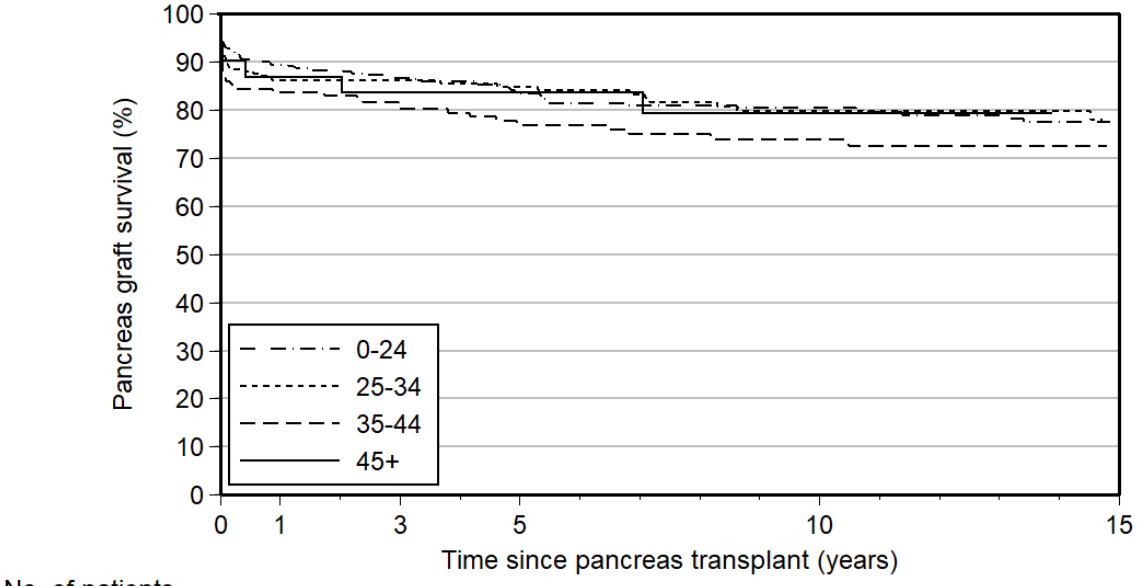
Figure 2.9: Pancreas survival censored for death with pancreas function, by donor BMI



No. of patients						
Underwight/Normal	502	410	335	283	193	111
Overweight	246	201	170	148	86	42
Obese	35	28	24	20	10	4

Pancreas survival by donor age is presented in Figure 2.10. The survival curves appear poorer for donors aged 35-44 compared with those 45 and older, or younger donors, but this difference was not statistically significant (p=0.5). We can only hypothesise that any difference may be due to donors over 45 being a more highly selected group, compared to the donors aged 35-44. One-year pancreas survival was 89.5% for transplants from donors aged 0-24 years, 86.1% for donors aged 25-34 years, 83.7% for donors aged 35-44 years, and 87.0% for donors aged 45+ years.

Figure 2.10: Pancreas transplant survival, censored for death with function, by donor age.



No. of patients

0-24	374	316	254	222	157	85
25-34	211	168	146	119	68	40
35-44	172	133	110	92	51	25
45+	31	26	23	22	17	11

Pancreas graft survival at 1 and 5 years post-transplant, censored at death and stratified by country and era of transplantation is presented in Table 2.8.

Table 2.8: Pancreas graft survival censored at death, by country and era

	Australia				New Zealand			
	1-year		*5-year*		*1-year*		*5-year*	
Era	*N*	*%*	*N*	*%*	*N*	*%*	*N*	*%*
2008-2013	175	90.2%	140	84.9%	15	100.0%	15	100.0%
2009-2014	182	88.7%	112	83.3%	13	92.3%	11	92.3%
2010-2015	190	88.3%	83	83.7%	14	92.9%	9	92.9%
2011-2016	206	89.1%	52	83.7%	15	93.3%	6	93.3%

Prevalence of functioning pancreas transplants

We calculated the point prevalence of people living in Australia and New Zealand who were alive with a functioning transplant on 31st December each year for the last five years (Table 2.7). The below numbers exclude people still alive, but whose pancreas transplant has failed. The number of functioning transplants is continuing to increase over time, as a consequence of the growing number of transplants, and their improved survival.

Table 2.9: People alive with a functioning pancreas transplant in Australia and New Zealand by year and residence, at year's end

State/country of residence	2013	2014	2015	2016	2017
New South Wales	100	110	122	130	141
Victoria	113	122	132	147	158
Queensland	82	91	93	100	108
South Australia	23	26	28	36	38
Western Australia	26	26	26	29	27
Tasmania	19	19	21	22	23
Australian Capital Territory	14	14	14	14	15
Northern Territory	1	2	4	4	4
New Zealand	35	33	34	38	42
Total	**413**	**443**	**474**	**520**	**556**

Kidney transplant survival

Kidney transplant survival was calculated for those who received SPK transplants, from the time of transplantation until the time of return to dialysis. We calculated both kidney failure including death with a functioning kidney and kidney failure censored for death with a functioning graft. For kidney graft survival we included only SPK transplants and excluded PAK transplant recipients. We had survival records for 780 SPK transplant recipients.

Figure 2.11 shows kidney survival censored for death. Over 7,428 years of observation, there were 89 kidney graft failures (excluding people who died with a functioning transplant). Overall, 1-year kidney graft survival was 96.9%, and 5-year survival 93.7%, and 10-year survival 88.4%.

Figure 2.11: Kidney transplant survival, censored for death with kidney function, for people receiving SPK transplants.

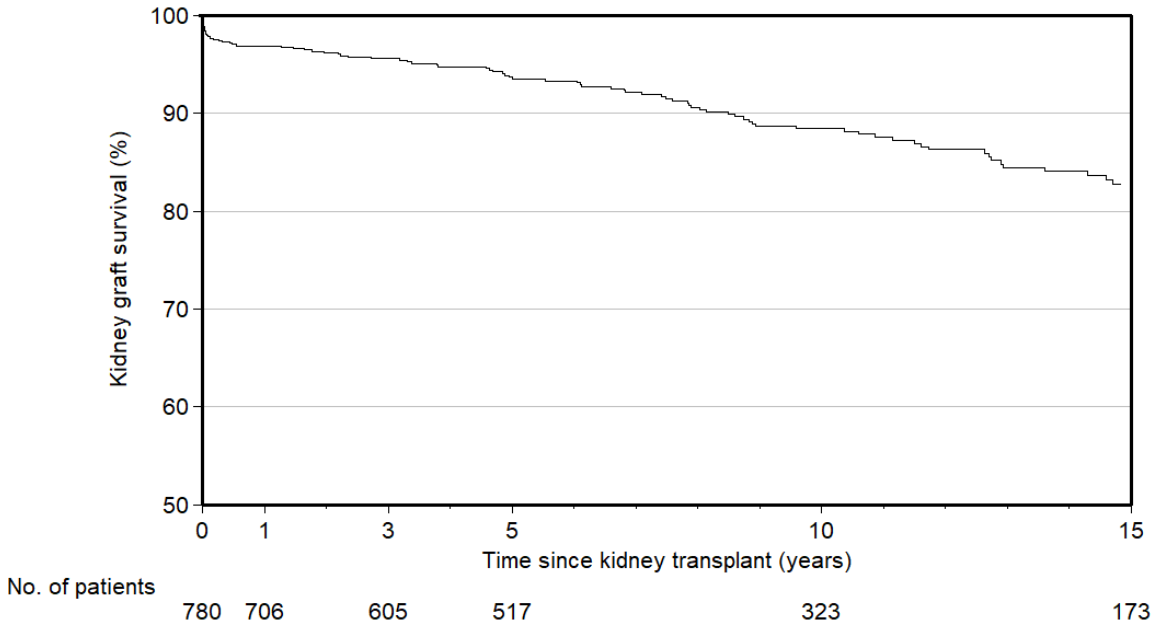
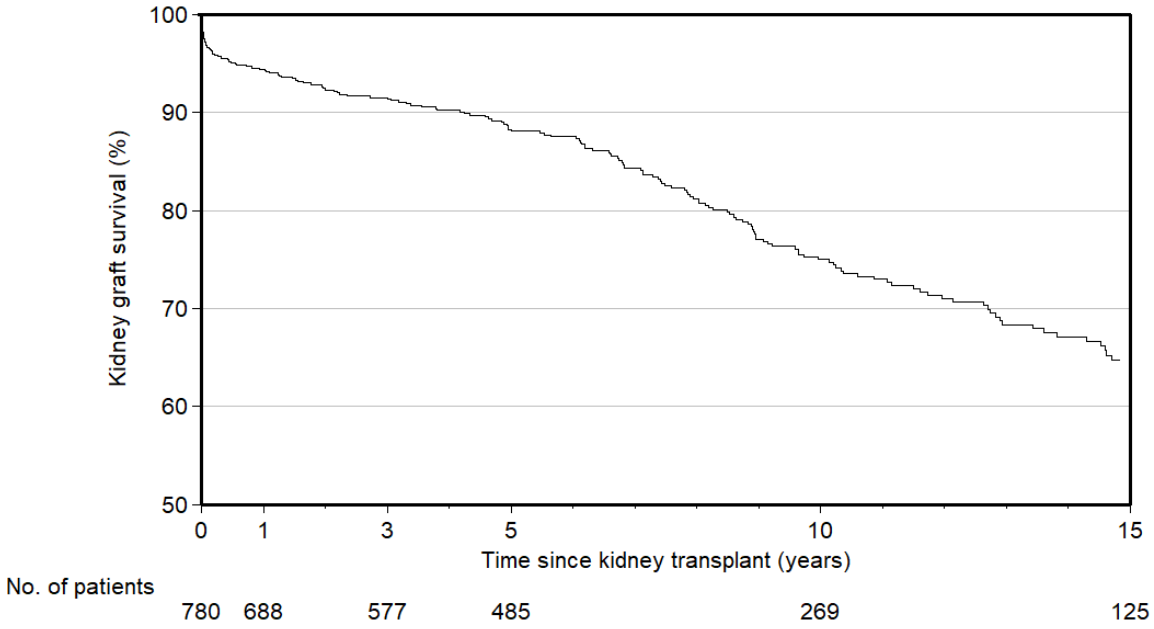


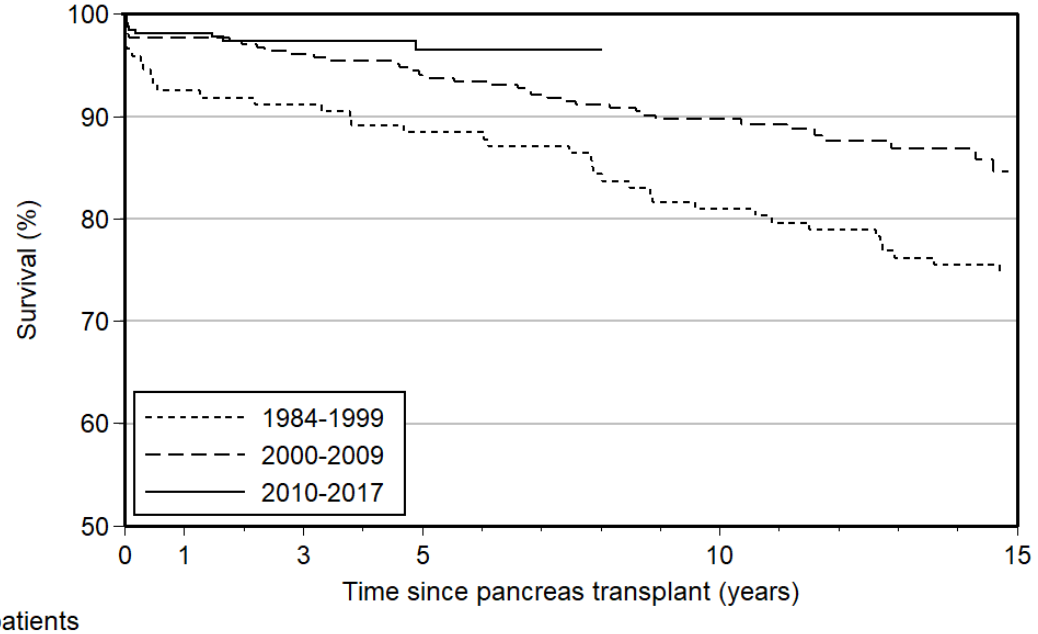
Figure 2.12 shows kidney survival including death with a functioning kidney. Over the same observation time there were 192 recipients who either died with kidney transplant function or experienced kidney graft failure. One, 5 and 10-year survival were 94.4%, 88.3% and 75.0% respectively.

Figure 2.12: Kidney transplant survival, including death with kidney function, for people receiving SPK transplants.



Kidney survival improved over time, with longer survival for those transplanted in more recent years (p=0.002). For those transplanted in 2000 or before, kidney transplant survival was 92.5% at 1 year and 88.4% at 5 years but was 98.2% at 1 year and 96.5% at 5 years for those transplanted in 2010 or later (Figure 2.13).

Figure 2.13: Kidney transplant survival, censored for death, for SPK recipients over time

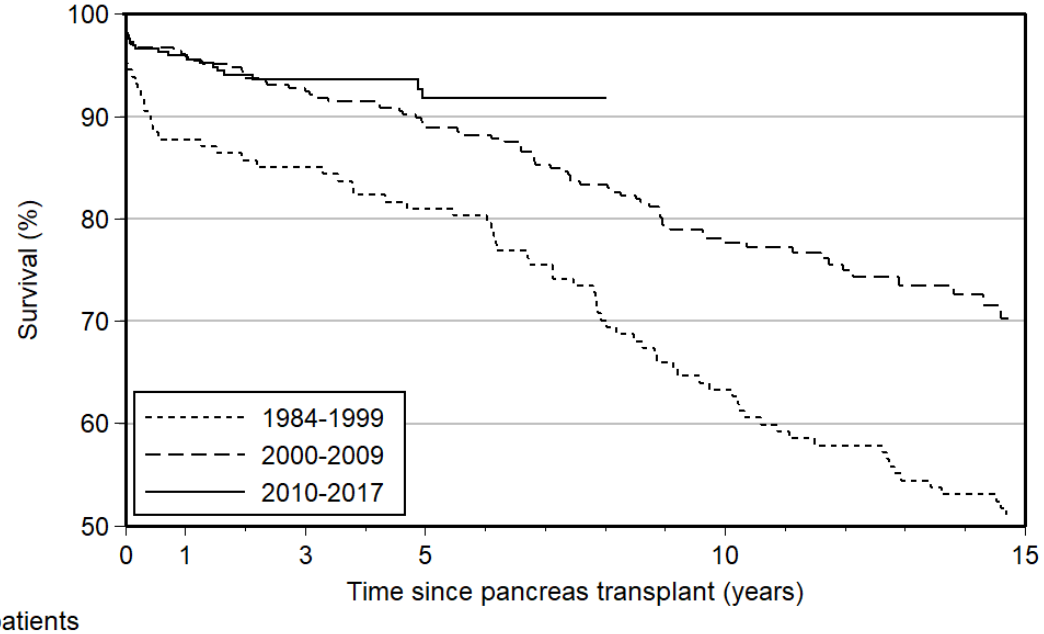


No. of patients

1984-1999	147	136	134	130	119	110
2000-2009	305	298	293	287	204	63
2010-2017	328	272	178	100	0	0

The era effect was even stronger when considering kidney failure including death with kidney function (p<0.001). For those transplanted before 2000, survival was 87.8% at 1 year and 81.0% at 5 years, but was 96.0% at 1 year and 91.8% at 5 years for those transplanted in 2010 or later (Figure 2.14).

Figure 2.14: Kidney transplant survival, including death with a functioning kidney, for SPK recipients over time



No. of patients

1984-1999	147	129	125	119	93	75
2000-2009	305	293	283	272	176	50
2010-2017	328	266	169	94	0	0

Pancreas transplant operative data

Characteristics of the pancreas transplant operations for 2017, previous years, and overall are shown in Table 2.8 below.

Table 2.10: Descriptive characteristics of pancreas transplant operations

	2017		1984-2016		Total	
Total patients (n)	52		757		809	
Pancreas graft						
Cold ischaemic time (hours)						
Patients (%)	48	(92)	686	(90)	734	(90)
Mean (SD)	7.6	(2.9)	10.3	(3.4)	10.1	(3.4)
Median (IQR)	7	(5, 10)	10	(8, 12)	10	(8, 12)
Anastomosis time (minutes)						
Patients (%)	51	(98)	648	(85)	699	(86)
Mean (SD)	18.7	(8)	30.1	(8)	29.3	(8.5)
Median (IQR)	20	(12.5, 26)	30	(25, 35)	30	(24, 34)
Exocrine drainage						
Enteric, n (%)	52	(100)	525	(69)	577	(71)
Bladder, n (%)	0	(0)	165	(21)	165	(20)
Unknown	0	(0)	67	(8)	67	(8)
Kidney graft						
Cold ischaemic time (hours)						
Patients (%)	31	(59)	670	(88)	701	(86)
Mean (SD)	9.6	(2.8)	10	(6.2)	10	(6.1)
Median (IQR)	10	(7, 12)	10	(7, 12)	10	(7, 12)
Anastomosis time (minutes)						
Patients (%)	51	(98)	607	(80)	658	(81)
Mean (SD)	20.8	(10.7)	32.4	(8.4)	31.5	(9.1)
Median (IQR)	22	(11.5, 29)	31	(27, 37)	31	(26, 37)
Kidney donor arteries						
One, n (%)	32	(61)	566	(74)	598	(73)
Two or more, n (%)	6	(11)	65	(8)	71	(8)
Unknown, n (%)	14	(26)	120	(15)	134	(16)

Totals show the number of patients with complete (non-missing) data

To investigate how much the total cold ischaemic time varied dependant on the donor state, and distance travelled to the transplanting centre, Table 2.9 displays a cross tabulation of donor state of origin with transplanting centre.

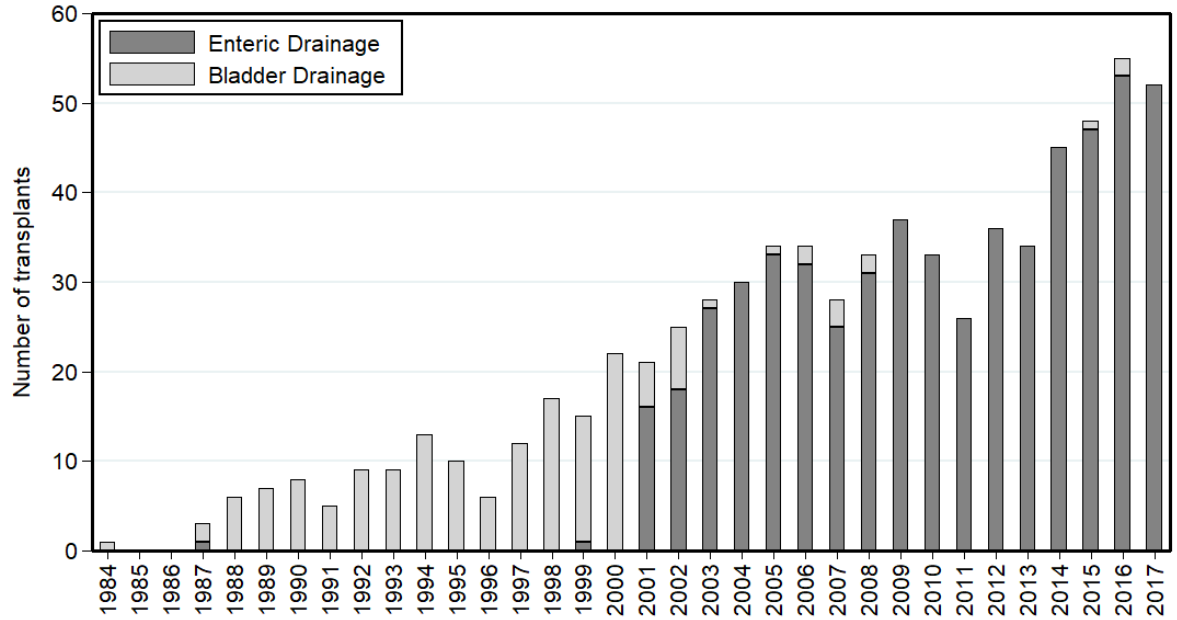
Table 2.11: Comparison of cold ischaemic time of Pancreas grafts by donor state, for Australian pancreas transplants 2017

Donor state	Pancreas grafts	Cold ischaemic time in hours, mean (SD)	
		Westmead (NSW)	*Monash (VIC)*
New South Wales	16	9.1 (2.9)	-
Victoria	14	-	5.1 (1.3)
Queensland	11	9.1 (2.5)	-
South Australia	2	-	5.0 (-)
Western Australia	2	9.5 (2.1)	-
Tasmania	1	-	5.0 (-)
Australian Capital Territory	2	8.5 (0.7)	-
Northern Territory	0	-	-
Total	52	9.1 (2.6)	5.1 (1.1)

Surgical technique

Exocrine drainage of the pancreas graft has changed over time. Enteric Drainage of the pancreas was first used in Australia and New Zealand during 2001. Figure 2.15 illustrates the number of transplants by pancreas duct management. Since 2001, most pancreas transplants have used enteric drainage of the pancreas duct.

Figure 2.15: Change in management of exocrine drainage of the pancreas over time



The site of donor vessel anastomoses onto the recipient vessels is dependent on many things, including but not limited to surgeon's preference, surgical ease of access, length and relative calibre of donor vessels. The sites of anastomosis for donor arteries and veins are displayed in Figure 2.16 and Figure 2.17 below.

Figure 2.16: Site of donor artery anastomosis onto recipient vessel

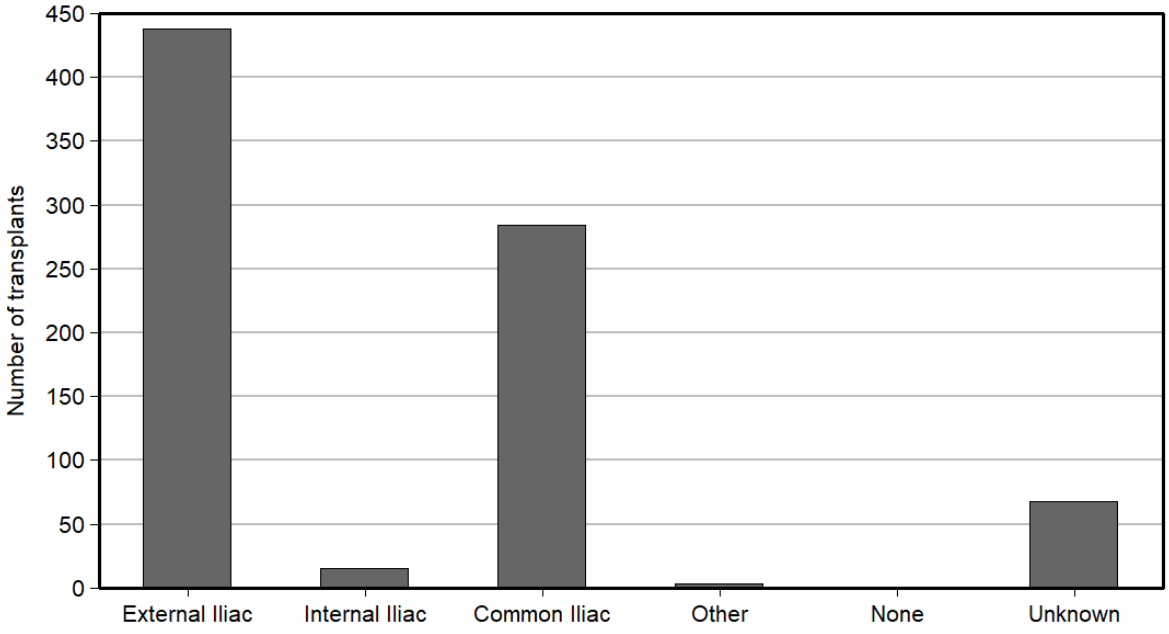
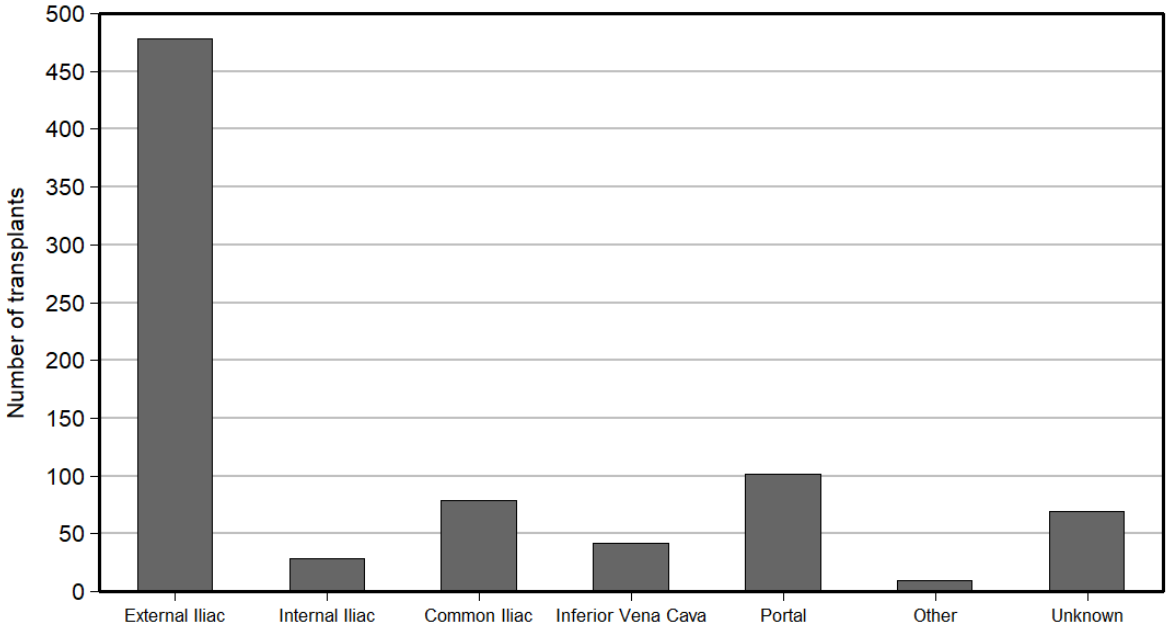


Figure 2.17: Site of donor vein anastomosis onto recipient vessel



The immunological matching of donor-recipient pairs is shown in Table 2.10, and the CMV and EBV matching is illustrated in Table 2.11.

Table 2.12: Immunological cross-matching of donor recipient pairs

	Donor-recipient pairs, n (column %)			
	Current		*Peak*	
Crossmatch				
T-cell Positive	0	(0)	0	(0)
B-cell Positive	3	(<1)	3	(<1)
T and B cell Negative	705	(87)	705	(87)
DTT Negative	1	(<1)	1	(<1)
None recorded	100	(12)	100	(12)
Panel Reactive Antibodies (%)				
0-24	93	(11)	91	(11)
25-49	5	(<1)	11	(1)
50+	1	(<1)	8	(<1)
Unknown	710	(87)	699	(86)

Table 2.13: Infectious disease serology cross-tabulation of donor recipient pairs

Recipient serology	**Donor serology, n (column %)**					
	Positive		*Negative*		*Unknown*	
CMV IgG						
Positive	80	(16)	35	(11)	2	(6)
Negative	5	(1)	5	(1)	2	(6)
Unknown	396	(82)	258	(86)	26	(86)
EBV IgG						
Positive	91	(19)	14	(19)	24	(8)
Negative	0	(0)	0	(0)	1	(<1)
Unknown	378	(80)	59	(80)	242	(90)

CMV, cytomegalovirus; EBV, Epstein-Barr virus; IgG, immunoglobulin G antibody

Chapter 3: Pancreas donors

Authors: Angela Webster, Paul Robertson, Tia Mark, James Hedley, Patrick Kelly

This chapter gives an overview of donors in 2017 and over time. Donor eligibility criteria guidelines are available in the TSANZ consensus statement http://www.tsanz.com.au/organallocationprotocols/ , but briefly require donors to be over 25kg, and up to the age of 45, without known diabetes mellitus or pancreatic trauma, or history of alcoholism or pancreatic trauma. Donation after cardiac death may be considered up to the age of 35. As these are guidelines, there may be occasions when there is minor deviation from these advised criteria.

Donor BMI is perceived as impacting recipient outcomes. Obese donors are more likely to have fatty pancreas, which results in more difficult surgery and increased post –operative complications, and suboptimal insulin secretion. Alcohol consumption is defined by a history of consumption of more than 40g/day. Table 3.1 describes pancreas donor characteristics in Australia and New Zealand to date.

Pancreas donor characteristics

Table 3.1: Demographics and characteristics of pancreas transplant donors

	Donors, n (column %)					
	2017		1984-2016		Total	
Age category						
0-24	20	(38)	354	(46)	374	(46)
25-34	15	(28)	196	(25)	211	(26)
35-44	12	(23)	160	(21)	172	(21)
45+	1	(1)	30	(3)	31	(3)
Unknown	4	(7)	17	(2)	21	(2)
Sex						
Female	17	(32)	278	(36)	295	(36)
Male	31	(59)	451	(59)	482	(59)
Unknown	4	(7)	28	(3)	32	(3)
BMI (kg/m2)						
Underweight/Normal (<24.9)	35	(67)	467	(61)	502	(62)
Overweight (25-29.9)	12	(23)	234	(30)	246	(30)
Obese (30+)	1	(1)	34	(4)	35	(4)
Unknown	4	(7)	22	(2)	26	(3)
Donor type						
Brain death (DBD)	46	(88)	745	(98)	791	(97)
Circulatory death (DCD)	1	(1)	9	(1)	10	(1)
Unknown	5	(9)	3	(<1)	8	(<1)
Donor mode of death						
Cerebral hypoxia/ischaemia	7	(13)	19	(2)	26	(3)
Cerebral infarct	0	(0)	12	(1)	12	(1)
Intracranial haemorrhage	4	(7)	148	(19)	152	(18)
Non-neurological condition	8	(15)	121	(15)	129	(15)
Other neurological condition	3	(5)	3	(<1)	6	(<1)
Traumatic brain injury	0	(0)	29	(3)	29	(3)
Unknown	30	(57)	425	(56)	455	(56)
Alcohol consumption						
Never	47	(90)	597	(78)	644	(79)
Former	0	(0)	4	(<1)	4	(<1)
Current	1	(1)	36	(4)	37	(4)
Unknown	4	(7)	120	(15)	124	(15)
Smoking history						
Never	34	(65)	476	(62)	510	(63)
Former	1	(1)	32	(4)	33	(4)
Current	13	(25)	179	(23)	192	(23)
Unknown	4	(7)	70	(9)	74	(9)
Donor's blood group						
O	22	(42)	361	(47)	383	(47)
A	17	(32)	259	(34)	276	(34)
B	7	(13)	70	(9)	77	(9)
AB	2	(3)	17	(2)	19	(2)
Unknown	4	(7)	50	(6)	54	(6)

	Donors, n (column %)					
	2017		1984-2016		Total	
Kidney biopsy						
Performed	22	(42)	154	(20)	176	(21)
Not performed	30	(57)	600	(79)	630	(77)
Unknown	0	(0)	3	(<1)	3	(<1)
CMV serology						
IgG positive	38	(73)	443	(58)	481	(59)
IgG Negative	10	(19)	288	(38)	298	(36)
Unknown	4	(7)	26	(3)	30	(3)
EBV serology						
IgG positive	40	(76)	429	(56)	469	(57)
IgG Negative	3	(5)	70	(9)	73	(9)
Unknown	9	(17)	258	(34)	267	(33)

DBD, donor after brain death; DCD, donor after circulatory death; CMV, cytomegalovirus; EBV, Epstein-Barr virus; IgG, immunoglobulin G antibody

The distribution of donor states of origin is shown in Table 3.2 and Table 3.3 by transplanting unit.

Table 3.2: Distribution of state of residence of pancreas donors in Australia over time at Westmead national pancreas transplant unit (NSW)

State	Donors, n (column %)													
	2017		*2016*		*2015*		*2014*		*2013*		*2012*		*Total*	
NSW	10	(50)	9	(42)	10	(47)	7	(41)	5	(35)	9	(45)	0	(0)
VIC	0	(0)	1	(4)	1	(4)	1	(5)	0	(0)	2	(10)	0	(0)
QLD	4	(20)	7	(33)	4	(19)	2	(11)	1	(7)	2	(10)	0	(0)
SA	1	(5)	0	(0)	3	(14)	5	(29)	5	(35)	5	(25)	0	(0)
WA	4	(20)	4	(19)	3	(14)	2	(11)	3	(21)	2	(10)	0	(0)
TAS	0	(0)	0	(0)	0	(0)	0	(0)	0	(0)	0	(0)	0	(0)
ACT	0	(0)	0	(0)	0	(0)	0	(0)	0	(0)	0	(0)	0	(0)
NT	1	(5)	0	(0)	0	(0)	0	(0)	0	(0)	0	(0)	0	(0)
Unknown	11	(55)	8	(38)	7	(33)	11	(64)	6	(42)	8	(40)	0	(0)
Total	20	(100)	21	(100)	21	(100)	17	(100)	14	(100)	20	(100)	0	(0)

Table 3.3: Distribution of state of residence of pancreas donors in Australia over time at Monash pancreas transplant unit (VIC)

State	Donors, n (column %)													
	2017		***2016***		***2015***		***2014***		***2013***		***2012***		***Total***	
NSW	0	(0)	0	(0)	0	(0)	1	(10)	5	(45)	2	(28)	0	(0)
VIC	15	(88)	12	(66)	13	(86)	7	(70)	6	(54)	5	(71)	0	(0)
QLD	1	(5)	0	(0)	0	(0)	0	(0)	0	(0)	0	(0)	0	(0)
SA	0	(0)	2	(11)	2	(13)	0	(0)	0	(0)	0	(0)	0	(0)
WA	1	(5)	3	(16)	0	(0)	1	(10)	0	(0)	0	(0)	0	(0)
TAS	0	(0)	1	(5)	0	(0)	1	(10)	0	(0)	0	(0)	0	(0)
ACT	0	(0)	0	(0)	0	(0)	0	(0)	0	(0)	0	(0)	0	(0)
NT	0	(0)	0	(0)	0	(0)	0	(0)	0	(0)	0	(0)	0	(0)
Unknown	0	(0)	4	(22)	2	(13)	5	(50)	2	(18)	2	(28)	0	(0)
Total	17	(100)	18	(100)	15	(100)	10	(100)	11	(100)	7	(100)	0	(0)

Donor and recipient state/territory

Table 3.4 and Table 3.5 show the distribution of donor organs according to state of origin, cross-tabulated with the state of origin of the recipients who received those organs, for 2017, and from inception of the pancreas program. Note, these tables include Australian donors and recipients only.

Table 3.4: Number of pancreas transplants by donor and recipient state of residence in Australia, all years

Recipient state	Donor state (number of transplants)									Total
	NSW	VIC	QLD	SA	WA	TAS	ACT	NT	Unknown	
NSW	106	7	16	20	15	0	0	0	65	229
VIC	18	138	1	5	3	4	0	0	49	218
QLD	56	8	20	22	9	0	0	1	30	146
SA	12	13	2	8	3	0	0	0	15	53
WA	16	2	11	5	5	0	0	0	12	51
TAS	12	6	1	1	0	1	0	0	6	27
ACT	11	1	1	2	0	0	0	0	8	23
NT	1	0	0	1	1	0	0	0	1	4
Total	232	175	52	64	36	5	0	1	186	751

Table 3.5: Number of pancreas transplants by donor and recipient state of residence in Australia, 2017 only

Recipient state	Donor state (number of transplants)									Total
	NSW	VIC	QLD	SA	WA	TAS	ACT	NT	Unknown	
NSW	5	0	1	1	3	0	0	0	6	16
VIC	0	14	0	0	0	0	0	0	0	14
QLD	3	0	3	0	0	0	0	1	4	11
SA	0	1	0	0	1	0	0	0	0	2
WA	1	0	0	0	1	0	0	0	0	2
TAS	0	0	1	0	0	0	0	0	0	1
ACT	1	0	0	0	0	0	0	0	1	2
NT	0	0	0	0	0	0	0	0	0	0
Total	10	15	5	1	5	0	0	1	11	48

Chapter 4: Islet cell transplants

Authors: Patricia Anderson, Natasha Rogers, James Hedley, Angela Webster, on behalf of the Australian Islet Consortium

Islet transplants are a treatment for type 1 diabetics who have hypoglycaemic unawareness and/or severe metabolic instability, are sensitive to insulin, but who have minimal or no kidney impairment. Whole donor pancreas organs are processed aiming to produce a concentrate of islet cells >4000 islet equivalent numbers (IEQ)/kg in a volume of <9ml. Islet transplant recipients generally require more than one islet transplant to become insulin independent.

Data for islet transplant donors and recipients in Australia are still sparse. The islet transplant program started in 2002. There are two islet isolation facilities in Australia; St Vincent's Hospital Melbourne in Victoria, and Westmead hospital in New South Wales. There are three active islet transplant centres; the National Pancreas Transplant Unit at Westmead Hospital, St Vincent's Hospital Melbourne, and the Royal Adelaide Hospital. There is no islet transplant program in New Zealand. This chapter contains information about allogenic islet transplants (i.e. islets from a deceased donor), whereas Chapter 5 contains information about autologous islet transplants (i.e. islets isolated from the recipient's own pancreas).

In this year's report we have added as much data as we have available on the islet program in Australia to date, and expanded description to capture the waiting list for islet transplants, donor and recipient characteristics. We have only reported islet donors and procedures that were intended to be used for an islet transplantation, and not islet isolation procedures that were undertaken only for research purposes. Some donor isolations intended for transplantation did not proceed to transplantation, generally because the pancreas processing failed set release criteria, with the major reason being insufficient concentration of islet cells.

The islet program waiting list is intentionally not long. Table 4.2 shows the number of patients referred for an islet transplant in 2017 by state of residence and the transplant centre they were referred to. Table 4.2 shows the number of patients accepted onto an islet waiting list during 2017, while Table 4.3 shows the islet waiting list activity over time.

Table 4.1: Referrals for allogenic islet transplant during 2017 by state of residence and transplant centre they were referred to

State of residence	Westmead	St. Vincent's	Royal Adelaide	Total
NSW	9	0	0	9
VIC	0	15	0	15
QLD	1	0	0	1
SA	0	0	6	6
WA	1	0	1	2
TAS	0	0	0	0
ACT	0	0	0	0
NT	0	0	0	0
Total	11	15	7	33

Table 4.2: Patients accepted onto a waiting list for an allogenic islet transplant during 2017 by state of residence and transplant centre they were referred to

State of residence	Westmead	St. Vincent's	Royal Adelaide	Total
NSW	4	0	0	4
VIC	0	4	0	4
QLD	0	0	0	0
SA	0	0	3	3
WA	0	0	0	0
TAS	0	0	0	0
ACT	0	0	0	0
NT	0	0	0	0
Total	4	4	3	11

Table 4.3: Islet waiting list status over time; Westmead Hospital (NSW), St Vincent's Hospital (VIC) Royal Adelaide Hospital (SA)

	Patients (n)			
	2017	***2016***	***2015***	***2014***
Waiting list activity				
Active list at beginning of year	15	13	12	7
Added to active list during the year	16	12	8	11
First transplant	10	7	6	9
Second transplant	2	5	4	2
Third transplant	5	0	1	0
Removed from active list during year	10	8	13	11
First transplant	4	3	11	9
Second transplant	3	6	6	4
Third transplant	5	0	1	0
Death while active on list	0	0	0	1
Death within 12 months of removal from list	0	0	0	0
Active waiting list at the end of year	12	15	13	12
Transplants to waiting list				
Recipients	10	1	13	9
Transplants	12	1	16	10
Under consideration but not active on list				
Eligible	8	9	3	4
Delay	5	1	4	1
Withdrawn	1	2	12	11
Long Term Follow Up	0	1	0	0
No Decision	4	1	0	0
Death	0	0	1	1
Other Reasons	4	6	7	3
Referred but declined for islet transplantation				
Not eligible	23	19	8	16

Note: Includes simultaneous islet kidney transplants. Some patients with multiple transplants in the same year were added and removed multiple times

Islet isolations

Sometimes when pancreas donations are processed for islet transplantation, the resulting islets do not meet transplant release criteria. The decision to proceed with transplantation is made once release testing is complete and the quality and quantity of islet cells is known. Islet isolation procedures follow good manufacturing procedure (GMP) guidelines as set out by the Australian Therapeutic Goods Administration (TGA). Isolations occur at one of two dedicated isolation facilities at Westmead (Sydney) and St. Vincent's Institute (SVI, Melbourne), both associated with their respective local hospitals Westmead and St. Vincent's Hospital. Occasionally preparations are sent between Melbourne and Sydney,

however Royal Adelaide Hospital has no islet isolation facility and is dependent on islets from either Westmead or St. Vincent's Institute, with the latter being is main provider of islets. A summary of islet cell isolation activity by centre and year in presented in Table 4.4.

Table 4.4: Summary of allogenic islet cell isolation activity, for all centres in Australia

Activity	2017	2002-2016	Total
Westmead (NSW)			
Pancreata donations discarded before isolation	3	3	6
Islet isolations	13	237	250
Islet isolations used for transplant	7	53	60
Islet isolations discarded	6	184	190
Islet recipients	6	33	37
St. Vincent's (VIC)			
Pancreata donations discarded before isolation	0	4	4
Islet isolations	10	128	138
Islet isolations used for transplant	5	39	44
Islet isolations discarded	5	89	94
Islet recipients	4	24	25

Some recipients with multiple transplants have received islets from both Westmead and St. Vincent's.

The donor characteristics of islet cell donor isolations are presented in Table 4.5 (Westmead Hospital), Table 4.6 (St. Vincent's Hospital), and Table 4.7 (Westmead and St Vincent's hospitals combined).

Table 4.5: Donor characteristics from allogenic islet isolations performed in Westmead Hospital (NSW)

	Donors (n)		
	2017	***2002-2016***	***Total***
Total	13	237	250
Age			
Mean (SD)	43.2 (12.1)	45.4 (12.8)	45.3 (12.8)
0-24	2	21	23
25-34	2	29	31
35-44	1	46	47
45+	8	140	148
Unknown	0	1	1
Sex			
Female	8	92	100
Male	5	142	147
Unknown	0	0	0
BMI kg/m^2			
Mean (SD)	32.5 (8.3)	28.5 (6.3)	28.7 (6.5)
Underweight (<18.5)	0	3	3
Normal weight (18.5-24)	3	78	81
Overweight (25-29)	2	81	83
Obese (30+)	8	74	82
Unknown	0	1	1
State of residence			
NSW	5	111	116
VIC	3	43	46
QLD	5	29	34
SA	0	34	34
WA	0	12	12
TAS	0	5	5
ACT	0	1	1
NT	0	0	0
Unknown	0	2	2
Donor type			
Brain death (DBD)	13	229	242
Circulatory death (DCD)	0	8	8

	Donors (n)		
	2017	*2002-2016*	*Total*
Donor mode of death			
Cerebral hypoxia/ischaemia	0	23	23
Cerebral infarct	1	10	11
Intracranial haemorrhage	9	107	116
Non-neurological condition	2	24	26
Other neurological condition	1	2	3
Traumatic brain injury	0	23	23
Unknown	0	40	40
Days ventilated prior to donation			
Mean	2.8 (1.4)	3.0 (2.5)	2.9 (2.5)
Alcohol consumption			
Current	3	9	12
Former	0	2	2
Never	10	122	132
Unknown	0	104	104
Smoking history			
Current	5	41	46
Former	1	2	3
Never	7	123	130
Unknown	0	71	71
Cultural and ethnic group			
Indigenous Australian or Torres Strait Islander	0	1	1
Maori or Pacific Islander	0	0	0
White	7	195	202
North East Asian (Chinese)	0	1	1
South East Asian	0	3	3
South and Central Asian (Indian)	0	1	1
Middle Eastern or North African	0	0	0
Other	0	2	2
Unknown	6	34	40
Blood group			
O	12	112	124
A	1	99	100
B	0	17	17
AB	0	8	8
Unknown	0	1	1
CMV serology			
IgG positive	12	98	110
IgG negative	1	79	80
Unknown	0	20	20

2 isolations were performed at Westmead for intended use in South Australia.

Table 4.6: Donor characteristics for allogenic islet isolations performed in St Vincent's Hospital (VIC)

	Patients (n)		
	2017	***2002-2016***	***Total***
Total	10	128	138
Age			
Mean (SD)	40.0 (11.6)	48.2 (13.3)	47.6 (13.3)
0-24	2	7	9
25-34	0	13	13
35-44	4	24	28
45+	4	84	88
Unknown	0	0	0
Sex			
Female	6	65	71
Male	4	63	67
Unknown	0	0	0
BMI kg/m^2			
Mean (SD)	27.7 (7.3)	29.1 (6.4)	29.0 (6.5)
Underweight (<18.5)	0	0	0
Normal weight (18.5-24)	4	31	35
Overweight (25-29)	3	39	42
Obese (30+)	3	58	61
Unknown	0	0	0
State of residence			
NSW	1	8	9
VIC	7	67	74
QLD	1	0	1
SA	1	35	36
WA	0	3	3
TAS	0	8	8
ACT	0	1	1
NT	0	6	6
Unknown	0	0	0
Donor type			
Brain dead (DBD)	10	120	130
Circulatory death (DCD)	0	8	8
Unknown	0	0	0
Donor mode of death			
Cerebral hypoxia/ischaemia	3	24	27
Cerebral infarct	0	11	11
Intracranial haemorrhage	7	56	63
Non-neurological condition	0	17	17
Other neurological condition	0	4	4
Traumatic brain injury	0	10	10
Unknown	0	6	6
Days ventilated prior to donation			
Mean (SD)	3.1 (2.0)	3.1 (2.0)	3.1 (2.0)

	Patients (n)		
	2017	*2002-2016*	*Total*
Alcohol consumption			
Current	8	45	53
Former	0	1	1
Never	2	29	31
Unknown	0	53	53
Smoking history			
Current	6	47	53
Former	1	2	3
Never	2	36	38
Unknown	1	43	44
Cultural and ethnic group			
Indigenous Australian or Torres Strait Islander	0	0	0
Maori or Pacific Islander	0	1	1
White	8	39	47
North East Asian (Chinese)	0	0	0
South East Asian	1	0	1
South and Central Asian (Indian)	0	0	0
Middle Eastern or North African	0	0	0
Other	0	0	0
Unknown	1	88	89
Blood group			
O	6	75	81
A	1	40	41
B	0	9	9
AB	1	4	5
Unknown	2	0	2
CMV serology			
IgG positive	5	40	45
IgG negative	3	36	39
Unknown	2	52	54

Table 4.7: Donor characteristics for allogenic islet isolations (all centres)

	Patients (n)		
	2017	***2002-2016***	***Total***
Total	23	365	388
Age			
Mean (SD)	41.8 (11.7)	46.3 (13.0)	46.1 (13.0)
0-24	4	28	32
25-34	2	42	44
35-44	5	70	75
45+	12	224	236
Unknown	0	1	1
Sex			
Female	14	157	171
Male	9	205	214
Unknown	0	0	0
BMI kg/m^2			
Mean (SD)	30.4 (8.0)	28.7 (6.3)	28.8 (6.5)
Underweight (<18.5)	0	3	3
Normal weight (18.5-24)	7	109	116
Overweight (25-29)	5	120	125
Obese (30+)	11	132	143
Unknown	0	1	1
State of residence			
NSW	6	119	125
VIC	10	110	120
QLD	6	29	35
SA	1	69	70
WA	0	15	15
TAS	0	13	13
ACT	0	2	2
NT	0	6	6
Unknown	0	2	2
Donor type			
Brain dead (DBD)	23	349	372
Circulatory death (DCD)	0	16	16
Unknown	0	0	0
Donor mode of death			
Cerebral hypoxia/ischaemia	3	47	50
Cerebral infarct	1	21	22
Intracranial haemorrhage	16	163	179
Non-neurological condition	2	41	43
Other neurological condition	1	6	7
Traumatic brain injury	0	33	33
Unknown	0	46	46
Days ventilated prior to donation			
Mean (SD)	2.9 (1.7)	3.0 (2.3)	3.0 (2.3)

	Patients (n)		
	2017	*2002-2016*	*Total*
Alcohol consumption			
Current	11	54	65
Former	0	3	3
Never	12	151	163
Unknown	0	157	157
Smoking history			
Current	11	88	99
Former	2	4	6
Never	9	159	168
Unknown	1	114	115
Cultural and ethnic group			
Indigenous Australian or Torres Strait Islander	0	1	1
Maori or Pacific Islander	0	1	1
White	15	234	249
North East Asian (Chinese)	0	1	1
South East Asian	1	3	4
South and Central Asian (Indian)	0	1	1
Middle Eastern or North African	0	0	0
Other	0	2	2
Unknown	7	122	129
Blood group			
O	18	187	205
A	2	139	141
B	0	26	26
AB	1	12	13
Unknown	2	1	3
CMV serology			
IgG positive	17	138	155
IgG negative	4	115	119
Unknown	2	72	74

Donors who provided pancreatata that resulted in islet isolations that proceeded to transplantation are summarised in Table 4.8.

Table 4.8: Donor characteristics for allogenic islet isolations which resulted in transplantation in 2017

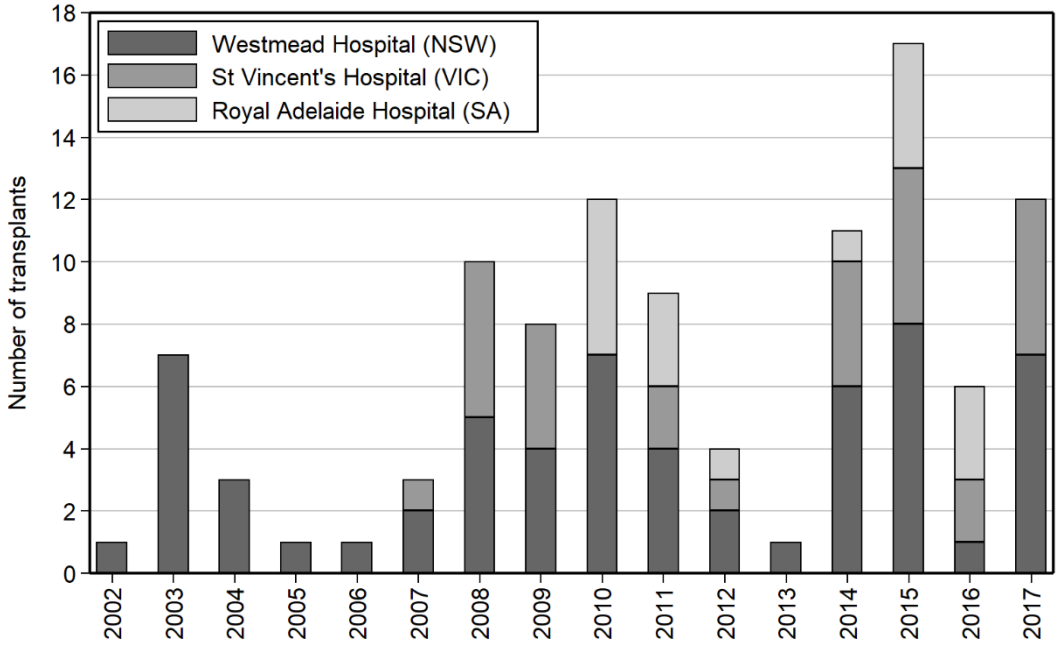
	Donors (n)		
	Westmead Hospital	*St. Vincent's Hospital*	*Total*
Total	7	4	11
Age			
Mean (SD)	40.0 (14.3)	47 (3.7)	42.5 (11.8)
0-24	2	0	2
25-34	1	0	1
35-44	1	1	2
45+	3	3	6
Sex			
Female	3	2	5
Male	4	2	6
BMI kg/m^2			
Mean (SD)	31.2 (16.1)	27.6 (3.1)	29.9 (12.7)
Underweight (<18.5)	1	0	1
Normal weight (18.5-24)	1	1	2
Overweight (25-29)	1	2	3
Obese (30+)	4	1	5
State of residence			
NSW	2	0	2
VIC	2	4	6
QLD	2	0	2
SA	0	0	0
WA	1	0	1
TAS	0	0	0
ACT	0	0	0
NT	0	0	0
Donor type			
Brain dead (DBD)	7	4	11
Circulatory death (DCD)	0	0	0
Donor mode of death			
Cerebral hypoxia/ischaemia	0	1	1
Cerebral infarct	1	0	1
Intracranial haemorrhage	4	3	7
Non-neurological condition	2	0	2
Other neurological condition	0	0	0
Traumatic brain injury	0	0	0
Days ventilated prior to donation			
Mean (SD)	3.3 (1.8)	3.1 (1.7)	3.2 (1.7)
Cold ischaemia time (hours)			
Mean (SD)	8.6 (5.0)	4.9 (1.0)	7.3 (4.3)

	Donors (n)		
	Westmead Hospital	***St. Vincent's Hospital***	***Total***
Alcohol consumption			
Current	2	4	6
Former	0	0	0
Never	3	0	3
Unknown	2	0	2
Smoking history			
Current	2	4	6
Former	1	0	1
Never	3	0	3
Unknown	1	0	1
Cultural and ethnic group			
Indigenous Australian	0	0	0
Maori or Pacific Islander	0	0	0
White	7	4	11
North East Asian (Chinese)	0	0	0
South East Asian	0	0	0
South and Central Asian (Indian)	0	0	0
Middle Eastern or North African	0	0	0
Other	0	0	0
Blood group			
O	7	0	7
A	0	4	4
B	0	0	0
AB	0	0	0
CMV serology			
IgG positive	5	2	7
IgG negative	2	2	4

Islet transplant recipients

Figure 4.1 illustrates the number of islet cell transplants in Australia between 2002 and 2017. The transplants were performed in Westmead (58), St Vincent's (29), and Royal Adelaide (17) Hospitals. In 2017, 7 transplants were performed at Westmead, 5 at St Vincent's and none at the Royal Adelaide.

Figure 4.1: Allogenic islet transplant activity 2002-2017, by transplanting centre



The characteristics of donor and recipient matches according to blood group are presented in Table 4.9, Table 4.10, and Table 4.11.

Table 4.9: Cross tabulation of recipient and donor blood groups, 2002-2017, from allogenic islet transplants undertaken in Westmead Hospital (NSW)

Recipient blood group	Donor blood group				Total
	O	*A*	*B*	*AB*	
O	17	0	0	0	17
A	9	21	0	0	30
B	0	0	5	0	5
AB	0	2	1	3	6
Unknown	2	0	0	0	2
Total	28	23	6	3	60

Recipients received more than 1 transplant therefore recipients may be duplicated in numbers

Table 4.10: Cross tabulation of recipient and donor blood groups, 2002-2017, from allogenic islet transplants undertaken in St Vincent's hospital (VIC)

Recipient blood group	Donor blood group				Total
	O	*A*	*B*	*AB*	
O	10	0	0	0	10
A	3	7	0	0	10
B	3	0	3	0	6
AB	0	1	0	1	2
Unknown	0	0	0	0	0
Total	16	8	3	1	28

26 isolations performed at St. Vincent's hospital, and 2 isolations performed at Westmead

Table 4.11: Cross tabulation of recipient and donor blood groups, 2002-2017, from allogenic islet transplants undertaken in Royal Adelaide Hospital (SA)

Recipient blood group	Donor blood group				Total
	O	*A*	*B*	*AB*	
O	8	0	0	0	8
A	3	8	0	0	11
B	0	0	2	0	2
AB	0	0	0	0	0
Unknown	0	0	0	0	0
Total	11	8	2	0	21

18 isolations performed at St Vincent's hospital, and 3 isolations performed at Westmead hospital

The characteristics of donor and recipient matches according to sex and blood group distributions for all centres are presented in Table 4.12 and Table 4.13.

Table 4.12: Cross tabulation of recipient and donor sex, 2002-2017*

Recipient sex	Donor sex		Total
	Female	Male	
Female	29	41	70
Male	14	20	34
Total	46	63	104

This includes 60 isolations at Westmead, and 44 isolations at St. Vincent's only. Recipients could receive more than one transplant and therefore may be duplicated in numbers

Table 4.13: Cross tabulation of recipient and donor blood groups, 2002-2017, for allogenic islet transplants undertaken in Australia

Recipient blood group	Donor blood group				Total
	O	*A*	*B*	*AB*	
O	32	0	0	0	32
A	15	35	0	0	50
B	3	0	8	0	11
AB	0	4	1	4	9
Unknown	2	0	0	0	2
Total	52	39	9	4	104

This includes 60 isolations at Westmead, and 44 isolations at St. Vincent's only. Recipients could receive more than one transplant and therefore may be duplicated in numbers

State of residence of recipients receiving an islet transplant in 2017, by the order of their transplant is presented in Table 4.14.

Table 4.14: Allogenic islet transplant recipients by state of residence and number of transplants received (all centres, 2017)

Recipient state of residence	*1st*	*2nd*	*3rd*	*Total*
NSW	3	3	1	7
VIC	1	0	3	4
QLD	0	0	0	0
SA	0	0	0	0
WA	0	0	0	0
TAS	0	0	0	0
ACT	0	0	0	0
NT	0	0	0	0
Unknown	0	0	1	1
Total	4	3	5	12

The states of residence of donors and recipients for each transplantation are shown Table 4.15 and Table 4.16, stratified by the transplant centre.

Table 4.15: Cross tabulation of allogenic islet donor and recipient state of residence in 2017

Recipient state of residence	Donor state of residence								
	NSW	VIC	QLD	SA	WA	TAS	ACT	NT	Total
NSW	1	2	2	0	0	0	0	0	5
VIC	0	4	0	0	0	0	0	0	4
QLD	1	0	0	0	0	0	0	0	1
SA	0	0	0	0	0	0	0	0	0
WA	0	0	0	0	0	0	0	0	0
TAS	0	0	0	0	0	0	0	0	0
ACT	0	0	0	0	0	0	0	0	0
NT	0	0	0	0	0	0	0	0	0
Total	2	6	2	0	0	0	0	0	10

This includes 6 recipients at Westmead, 4 recipients at Melbourne, and 0 recipients at Royal Adelaide.
Recipients could receive more than one transplant and therefore may be duplicated in numbers

Table 4.16: Cross tabulation of allogenic islet donor and recipient state of residence 2002-2017

Recipient state of residence	Donor state of residence								
	NSW	VIC	QLD	SA	WA	TAS	ACT	NT	Total
NSW	16	9	2	4	0	0	0	0	31
VIC	0	21	2	5	0	2	0	1	31
QLD	5	2	1	0	0	0	0	0	8
SA	5	7	1	9	1	2	0	0	25
WA	3	0	2	1	0	0	0	0	6
TAS	0	0	1	1	0	0	0	0	2
ACT	0	0	0	1	0	0	0	0	1
NT	0	0	0	0	0	0	0	0	0
Total	29	39	9	21	1	4	0	1	104

This includes 58 recipients at Westmead, 29 recipients at Melbourne, and 17 recipients at Royal Adelaide.
Recipients could receive more than one transplant and therefore may be duplicated in numbers

Characteristics of Islet recipients over time are shown in Table 4.17.

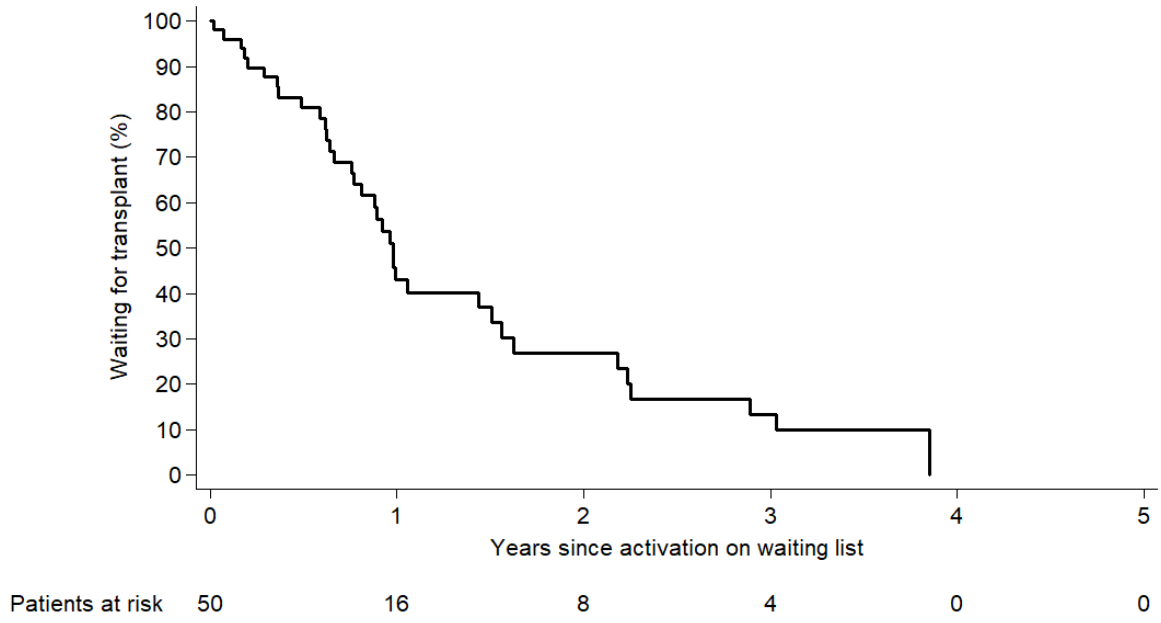
Table 4.17: Characteristics of allogenic islet cell transplant recipients in Australia by year of first transplant

	Patients (n)		
	2017	***2002-2016***	***Total***
Total	4	58	62
Age			
Mean (SD)	48.3 (10.8)	58.7 (11.0)	54.5 (11.6)
0-24	0	0	0
25-34	0	1	1
35-44	1	5	6
45+	3	0	3
Unknown	0	52	52
Sex			
Female	2	41	43
Male	2	17	19
State of residence			
NSW	3	21	24
VIC	1	14	15
QLD	0	1	1
SA	0	13	13
WA	0	0	0
TAS	0	1	1
ACT	0	0	0
NT	0	0	0
Unknown	0	8	8
Blood group			
O	1	11	12
A	3	15	18
B	0	3	3
AB	0	2	2
Unknown	0	27	27
Number of transplants per recipient			
1	3	14	17
2	1	24	25
3	0	20	20
Wait time from listing to first transplant			
1 year	3	20	23
2 years	0	3	3
3+ years	1	4	5
Unknown	0	31	31
Insulin independent post-transplant			
Yes	0	18	18
No	4	40	44

Insulin independence defined as being free from insulin use for 14 or more consecutive days

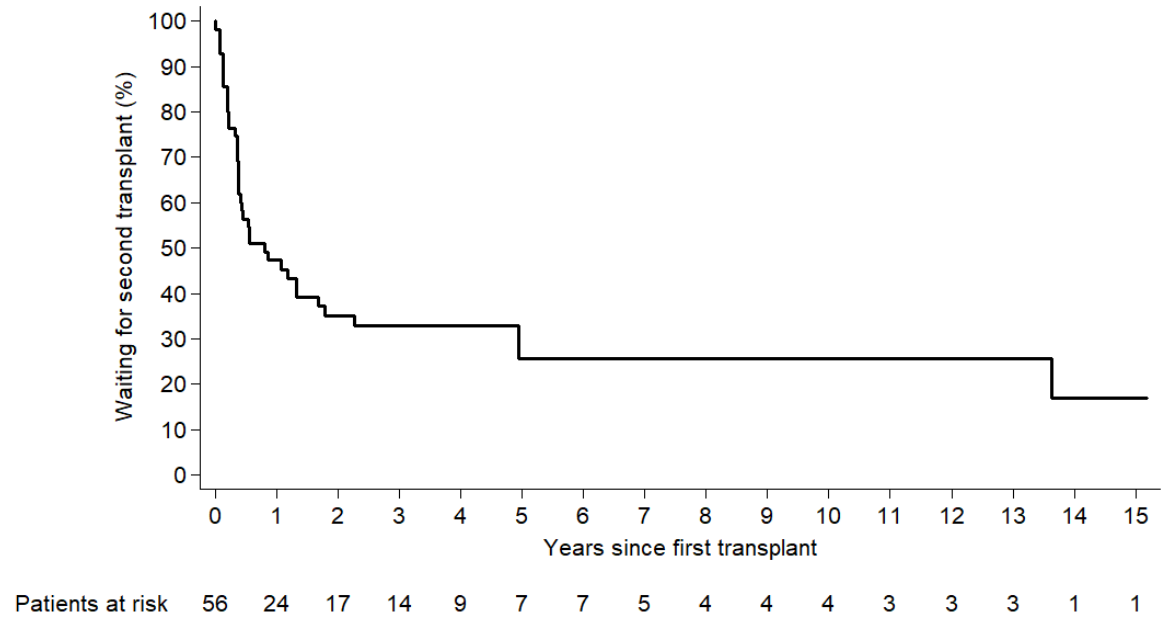
The time from activation on the waiting list to first islet transplant for 2002-2017 is presented in Figure 4.2. Data were available for 91 patients added to the waiting list before 31st December 2017, 56 of whom have received at least one transplant during this period. However, the date of waitlisting is known for only 50 patients, 35 of whom received at least one transplant as of 31st December 2017. Recipients waited a median of 0.98 years from activation on the waiting list to receiving their first transplant (IQR 0.62-2.18 years).

Figure 4.2: Time from activation on a waiting list to first allogenic islet transplant



The time from first to second islet transplant for 2002-2017 is presented in Figure 4.3. Recipients waited a median of 0.80 years from first transplant to receiving a second transplant (IQR 0.32-13.63 years).

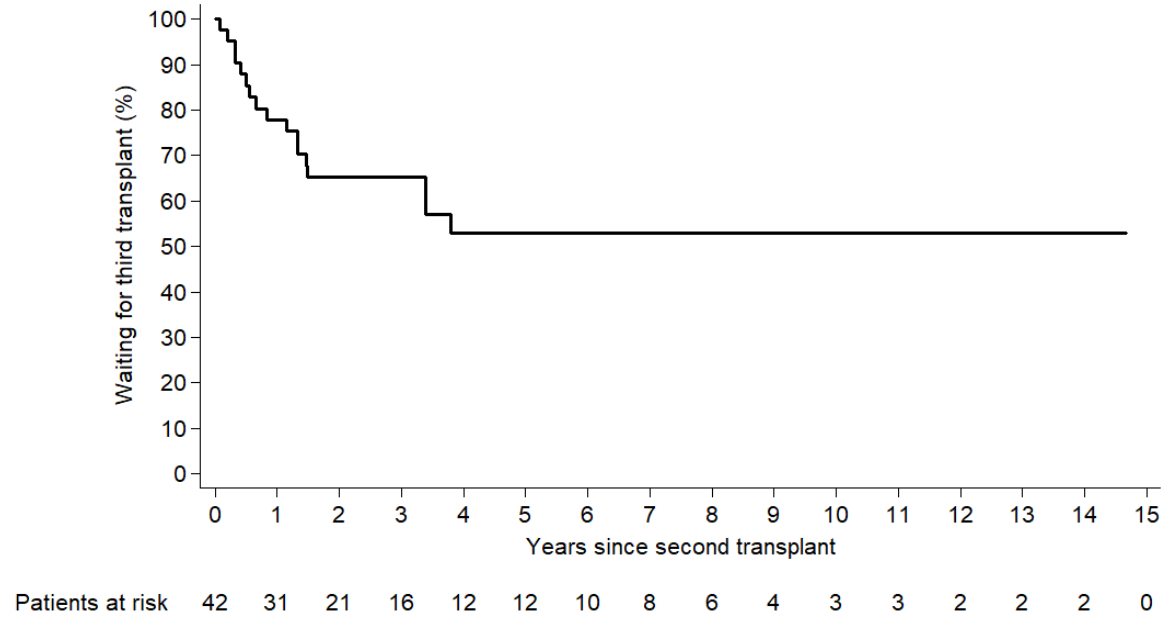
Figure 4.3: Time from first to second allogenic islet transplant



This figure includes some patients who do not require a second transplant, and hence will never receive one

The time from second to third islet transplant for 2002-2017 is presented in Figure 4.4. The median time from second transplant to third transplant has not yet been reached (25th percentile 1.33 years), likely due to many recipients not requiring a third transplant.

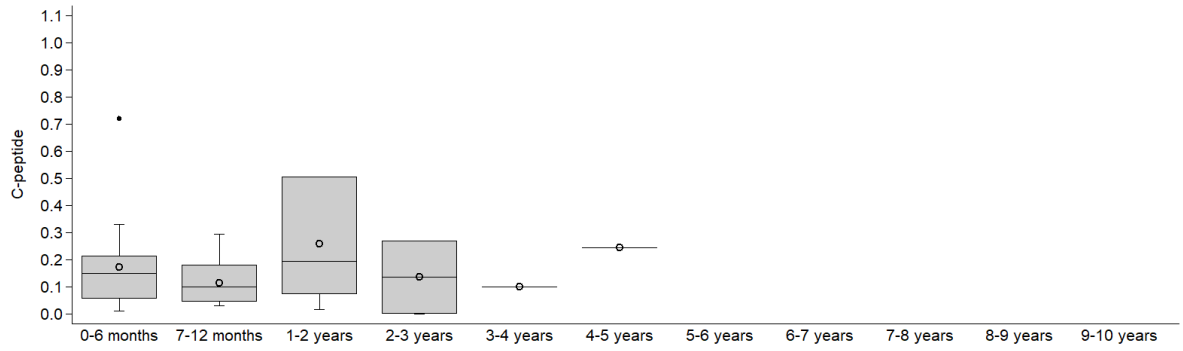
Figure 4.4: Time from second to third allogenic islet transplant



This figure includes some patients who do not require a third transplant, and hence will never receive one

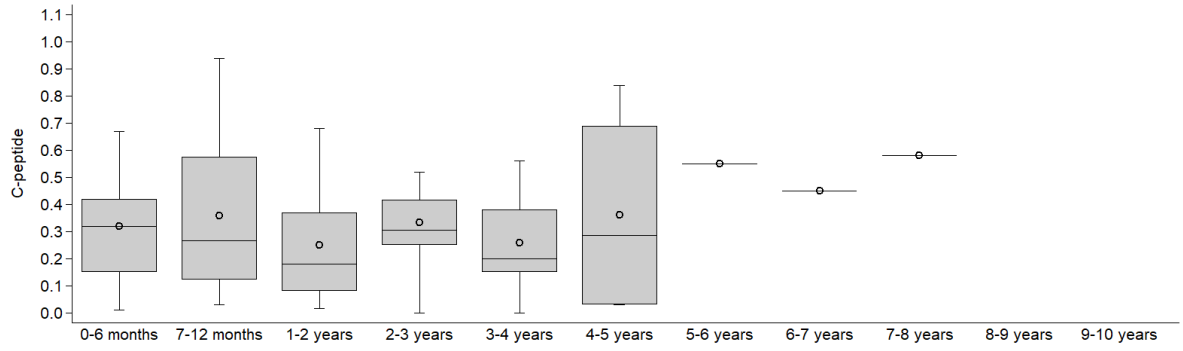
C-peptide is a protein that is released with insulin produced by the pancreas. Insulin given as a drug by injection does not have c-peptide attached. This means c-peptide can be used as a biomarker of insulin secretion, and so a way of measuring whether an islet transplant has been successful. A greater amount of c-peptide suggests a greater amount of insulin is being secreted. C-peptide is measured in ng/ml. The normal range for a non-diabetic person is approximately 0.7-3.1 ng/ml. The distribution of c-peptide measurements over time after first islet infusion (but before second islet infusion) is presented in Figure 4.5; the distribution of c-peptide measurements over time after second islet infusion (but before third islet infusion) is presented in Figure 4.6; and the distribution of c-peptide measurements over time after third islet infusion is presented in Figure 4.7.

Figure 4.5: Distribution of c-peptide over time since first allogenic islet infusion



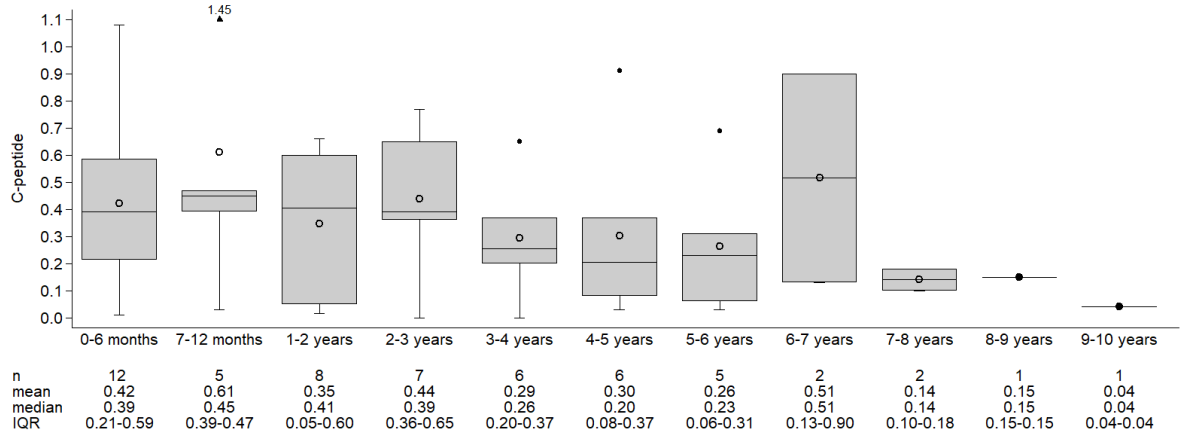
	0-6 months	7-12 months	1-2 years	2-3 years	3-4 years	4-5 years	5-6 years	6-7 years	7-8 years	8-9 years	9-10 years
n	19	9	3	2	1	1	0	0	0	0	0
mean	0.17	0.11	0.26	0.14	0.10	0.25	-	-	-	-	-
median	0.15	0.10	0.19	0.14	0.10	0.25	-	-	-	-	-
IQR	0.05-0.21	0.05-0.18	0.07-0.50	0.00-0.27	0.10-0.10	0.25-0.25	-	-	-	-	-

Figure 4.6: Distribution of c-peptide over time since second allogenic islet infusion



	0-6 months	7-12 months	1-2 years	2-3 years	3-4 years	4-5 years	5-6 years	6-7 years	7-8 years	8-9 years	9-10 years
n	19	12	11	4	5	4	1	1	1	0	0
mean	0.32	0.36	0.25	0.33	0.26	0.36	0.55	0.45	0.58	-	-
median	0.32	0.27	0.18	0.31	0.20	0.29	0.55	0.45	0.58	-	-
IQR	0.15-0.42	0.12-0.57	0.08-0.37	0.25-0.41	0.15-0.38	0.03-0.69	0.55-0.55	0.45-0.45	0.58-0.58	-	-

Figure 4.7: Distribution of c-peptide over time since third allogenic islet infusion



Typically, if a type 1 diabetic's blood sugars fall very low, they will experience symptoms, prompting them to self-treat by eating a source of carbohydrates. Very low blood sugar leads to symptoms such as confusion, slurred speech, erratic behaviour, sweating, and shakiness. One of the main indications for islet cell transplantation is lack of awareness of low blood sugars (hypoglycaemia), which can lead to death if untreated. Occurrence of unpredictable hypoglycaemia, particularly if frequent, can impact an individual's quality of life. Ryan et al (Diabetes 2004;53:955-962) proposed a symptom score to measure frequency, severity and degree of unawareness of hypoglycaemia experienced by diabetics. The HYPO score was stratified by the recorded level of glucose, and summed points for the type of symptoms experienced, whether the sufferer recognised the impending hypoglycaemia, and whether outside help was needed to recognise or treat each episode. A greater number of points were scored when glucagon was administered, or an ambulance called. The higher the HYPO score, the worse the impact of hypoglycaemia for an individual. A HYPO score of zero equates with no interference in regular life by hypoglycaemic episodes. The maximum score per hypoglycaemic episode was 198. The score over a month or a year is calculated by summing the scores for each documented episode of hypoglycaemia that occurred within that time frame. The full HYPO score scale is presented in the paper by Ryan et al (Diabetes 2004;53:955-962).

The distribution of HYPO score measurements over time after first islet infusion (but before second islet infusion) is presented in Figure 4.8, the distribution of HYPO score measurements over time after second islet infusion (but before third islet infusion) is

presented in Figure 4.9, and the distribution of HYPO score measurements over time after third islet infusion is presented in Figure 4.10.

Figure 4.8: Distribution of HYPO score over time since first allogenic islet infusion

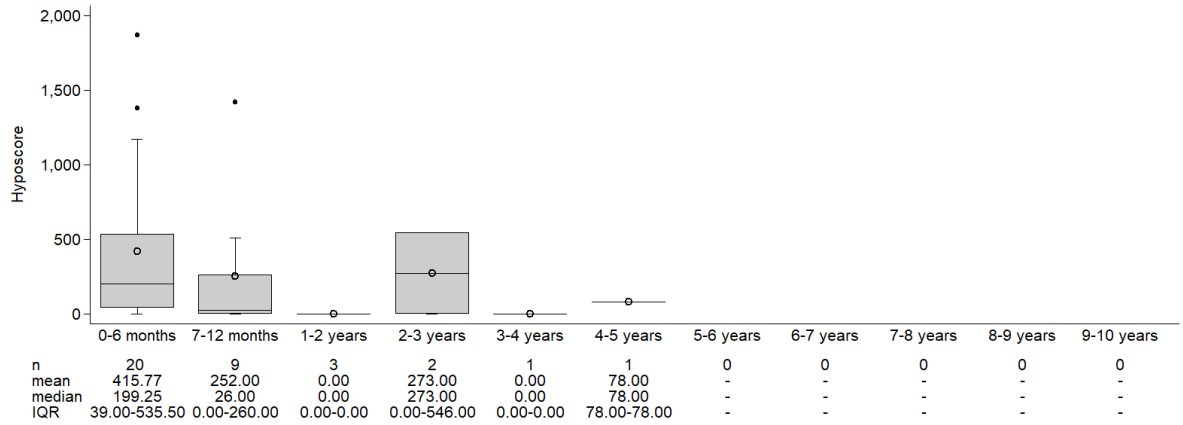


Figure 4.9: Distribution of HYPO score over time since second allogenic islet infusion

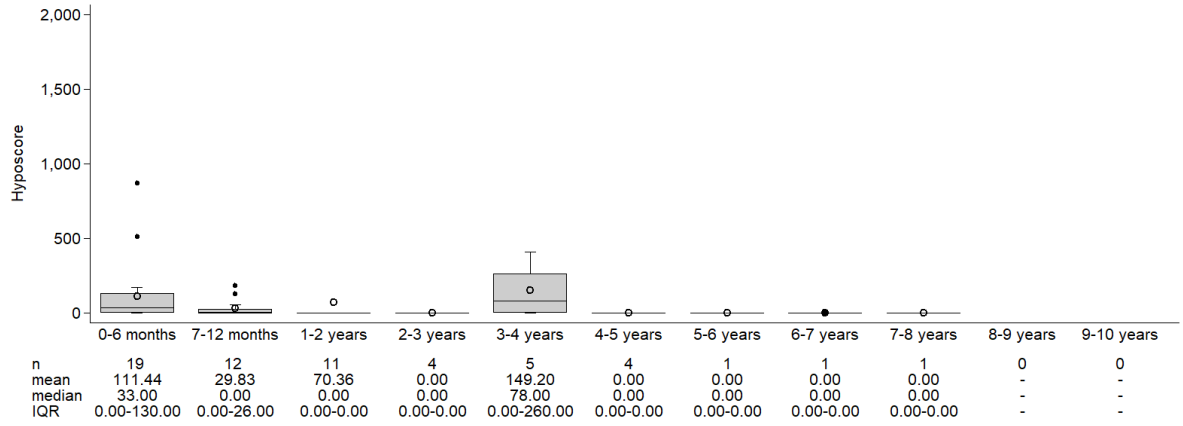
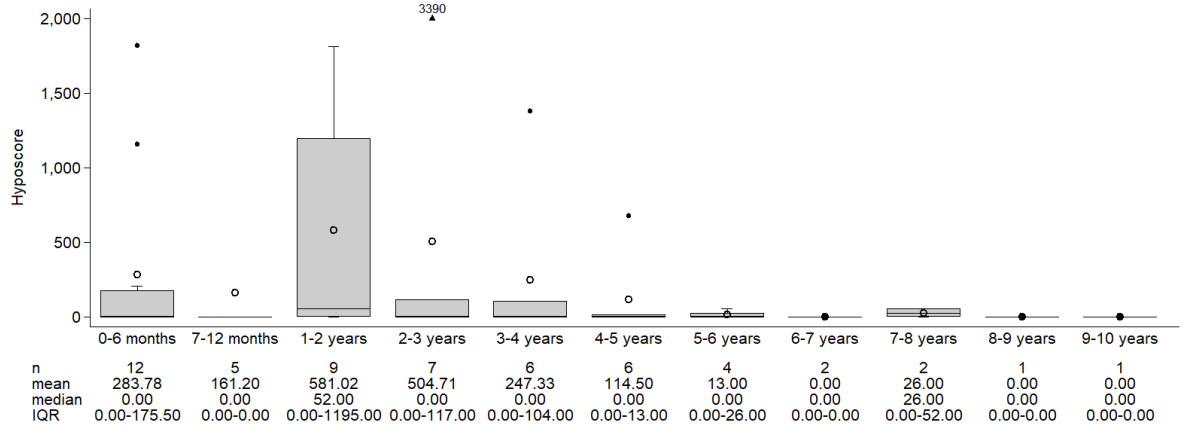
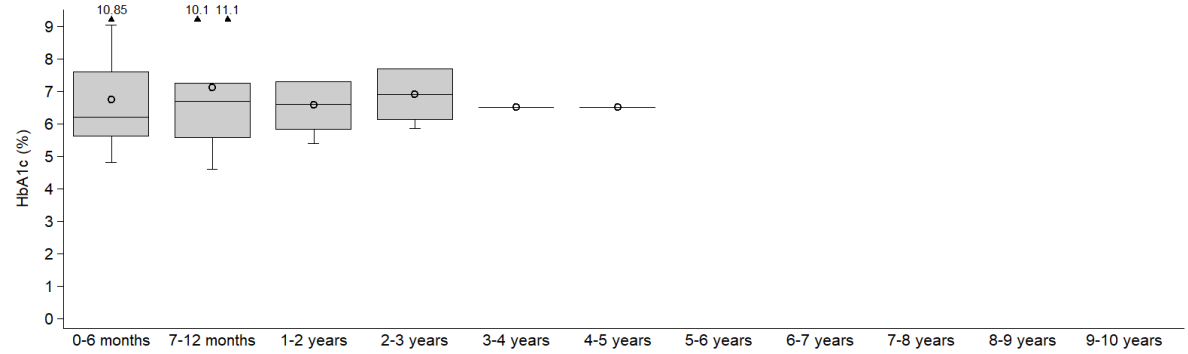


Figure 4.10: Distribution of HYPO score over time since third allogenic islet infusion



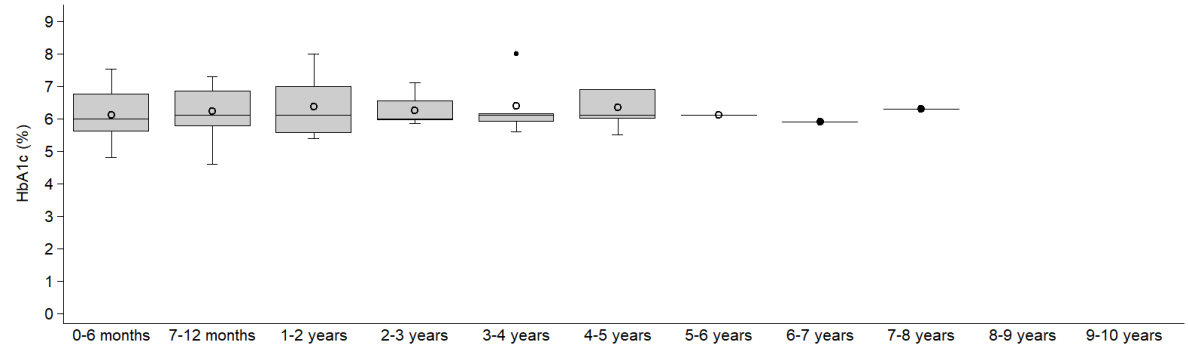
Glycated haemoglobin, known as HbA1C, is present in red blood cells, and can be used as a way of measuring a 3-month average of the plasma glucose level. This is helpful as a one-off glucose measurement may not reflect over all glucose control. HbA1C is measured and then converted to a proportion (%), with higher levels indicating poorer glucose control. HbA1c levels of 4-6% are generally regarded as reflecting non-diabetic control. The distribution of HbA1c measurements over time after first islet infusion (but before second islet infusion) is presented in Figure 4.11, the distribution of HbA1c measurements over time after second islet infusion (but before third islet infusion) is presented in Figure 4.12, and the distribution of HbA1c measurements over time third first islet infusion is presented in Figure 4.13.

Figure 4.11: Distribution of HbA1c (%) over time since first allogenic islet infusion



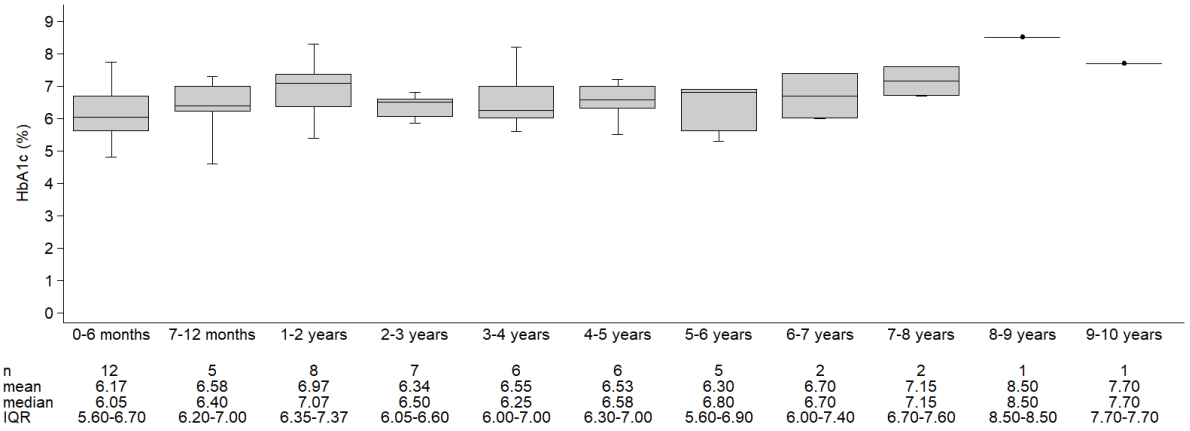
	0-6 months	7-12 months	1-2 years	2-3 years	3-4 years	4-5 years	5-6 years	6-7 years	7-8 years	8-9 years	9-10 years
n	19	9	3	2	1	1	0	0	0	0	0
mean	6.75	7.11	6.57	6.90	6.50	6.50	-	-	-	-	-
median	6.20	6.70	6.60	6.90	6.50	6.50	-	-	-	-	-
IQR	5.60-7.60	5.55-7.25	5.80-7.30	6.10-7.70	6.50-6.50	6.50-6.50	-	-	-	-	-

Figure 4.12: Distribution of HbA1c (%) over time since second allogenic islet infusion



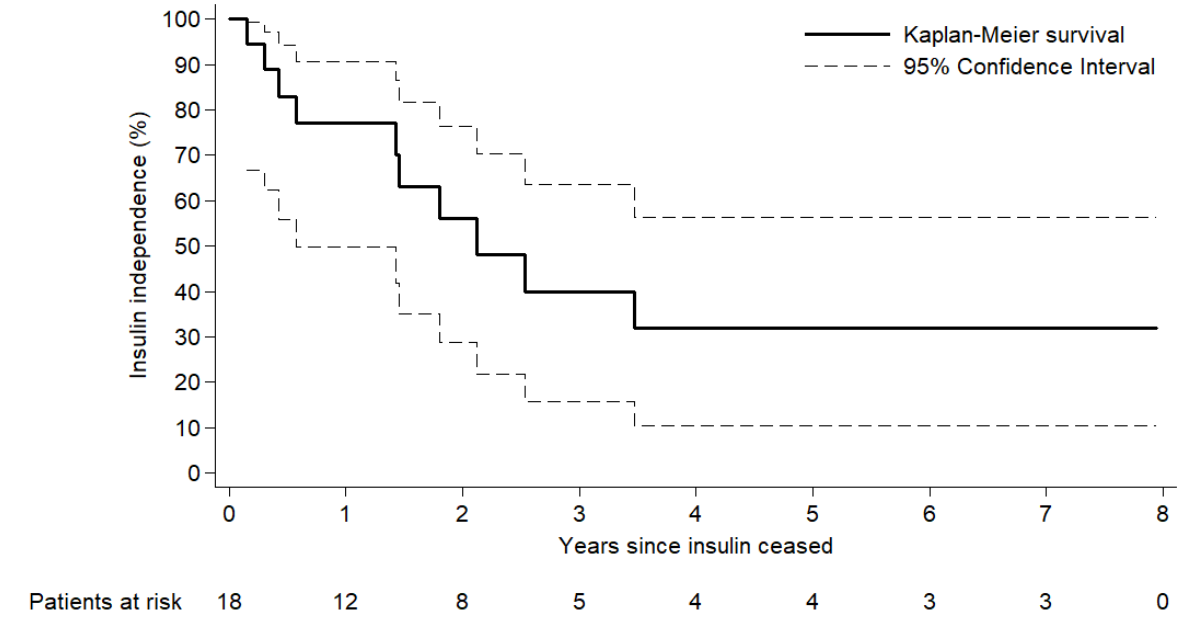
	0-6 months	7-12 months	1-2 years	2-3 years	3-4 years	4-5 years	5-6 years	6-7 years	7-8 years	8-9 years	9-10 years
n	19	12	11	4	5	3	1	1	1	0	0
mean	6.11	6.22	6.38	6.25	6.39	6.33	6.10	5.90	6.30	-	-
median	6.00	6.10	6.10	6.00	6.10	6.10	6.10	5.90	6.30	-	-
IQR	5.60-6.75	5.75-6.85	5.55-7.00	5.95-6.55	5.90-6.15	6.00-6.90	6.10-6.10	5.90-5.90	6.30-6.30	-	-

Figure 4.13: Distribution of HbA1c (%) over time since third allogenic islet infusion



Insulin independence is defined as a person being free from insulin use for at least 14 days. There are 18 patients who have achieved insulin independence; one patient after their first transplant, nine patients after their second transplant, and eight patients after their third transplant. The duration of insulin independence from the time insulin was first ceased for 2002-2017 is presented in Figure 4.14.

Figure 4.14: Duration of insulin independence from time first ceased



Chapter 5: Islet auto-transplants

Authors: Toby Coates, James Hedley, Angela Webster, on behalf of the Australian Islet Consortium

Autologous islet transplantation (auto-islet transplant) is an important and growing program, targeting a small number of people with rare diseases. This process is a treatment for people who have certain, often inherited, diseases of the pancreas which cause them severe and chronic pain. Chronic pancreatitis causes prolonged inflammation in the pancreas, and this in turn causes progressive scarring. It may also cause disturbed digestion and impaired growth in children, and as the disease progresses people may become diabetic. Often, people with this problem require very high doses of strong pain killers, and have reduced quality of life. Autologous islet transplantation is a process by which a person is their own donor. An individual's own pancreas is removed, the islet cells isolated, and then transplanted back into the patient. The main reason to do this is to reduce the chronic pain people experience and to improve their quality of life. Up to 40% of people undergoing an auto-islet transplant are insulin independent after the procedure, and another 30% show partial independence, the rest are insulin dependent. Auto-islet transplantation occurs in two Australian centres only; Westmead in NSW and The Royal Adelaide in South Australia. Since Adelaide does not have an Islet Isolation facility, the pancreas is sent to St. Vincent's institute Isolation facility and the islets are immediately returned for transplant in Adelaide, with a turn-around time of 5-6 hours.

Waiting list and isolation activity

Since auto-islet transplants do not require a donor, there is no waiting list for auto-islet transplant. However, not everyone referred for consideration of auto-islet transplant is suitable for the procedure. People with very long-standing chronic pancreatitis may have such a scarred pancreas that their islet cells have been destroyed. These people may benefit more from alternative treatments. For other people there may be reasons to wait a period of time before undergoing an auto-transplant. The number of patients waiting for an auto-islet transplant at each islet centre at the end of 2017 is presented in Table 5.1.

Table 5.1: Patients waiting for an auto-islet transplant at the end of 2017, by transplant centre

	Patients (n)
Westmead	
Under consideration	2
Accepted on the waiting list	0
Royal Adelaide	
Under consideration	4
Accepted on the waiting list	0

For auto-islet transplants occurring in Adelaide, the pancreactectomy happens in Adelaide, but the isolation procedure is done at St Vincent's hospital in Melbourne, after which the islet isolate is returned to Adelaide for the transplant to occur. The number of transplants performed in Australia by year across all islet centres is presented in Table 5.2.

Table 5.2: Auto-islet isolation/transplant activity by year

Year	Westmead	Royal Adelaide [1]	Total
2017	1	3	4
2016	0	1	1
2015	1	1	2
2014	0	0	0
2013	0	0	0
2012	0	0	0
2011	0	0	0
2010	1	0	1
Total	3	5	8

[1] Isolations performed at St. Vincent's Hospital

Patient characteristics

The characteristics of auto-islet transplant recipients by year of transplantation are presented in Table 5.3.

Table 5.3: Characteristics of auto-islet transplant recipients by year of transplant

	Mean (SD)		
	2017	***2002-2016***	***Total***
Patients (n)	3	5	8
Age	21.7 (8.1)	25.2 (17.9)	23.9 (14.3)
Patient weight	68.0 (12.5)	54.2 (23.2)	59.3 (20.1)
Pancreas weight	56.7 (22.9)	71.0 (64.7)	65.6 (50.9)
Islet equivalent (IEQ) total ('000)	475.3 (184.9)	175.4 (99.9)	287.9 (198.9)
Islet equivalent (IEQ) per kilogram ('000)	7.5 (4.1)	3.1 (1.9)	4.7 (3.5)

Chapter 6: Data quality

Authors: James Hedley, Patrick Kelly, Angela Webster

This chapter is a new addition to the annual report in 2018 and gives an overview of the quality of data used in this report. Throughout 2017 we have made efforts to improve data collection and management for the pancreas waiting list (Chapter 1), pancreas transplants (Chapters 2 and 3), and islet isolations and transplants (Chapter 4). The improvements to these three databases are discussed below. We are continuing these efforts in 2018 as well, and the long term aims of ANZIPTR in terms of data management are also discussed below.

Pancreas waiting list

To improve data capture across all three pancreas transplant units in Australia and New Zealand, we created a database using REDCap electronic data capture tools hosted securely at The University of Sydney. We consulted with transplant coordinators to create reports for managing patients under review, as well as those listed for transplant. To ensure a smooth transition to the new database, we imported data for all patients who were on the waiting list as of 1st July 2017, or who were referred for listing on or after 1st January 2017. From 1st July 2017 onwards, all new referrals were entered into the database, and any changes to the listing status of previously referred patients were also updated in this database. We are continuing to monitor this database to ensure it meets the day-to-day needs of transplant coordinators whilst also capturing all important information required for annual reporting. As more pancreas waiting list data becomes available, we will be able to include more interesting analyses in this report, such as exploring outcomes of patients listed for transplant.

Pancreas transplants

Data for pancreas donors and recipients are stored together in a database called RISC at Westmead Hospital. Since most pancreas recipients receive a kidney at the same time, data for all SPK recipients is also captured independently by the Australian and New Zealand Dialysis and Transplant Registry (ANZDATA). We have approached ANZDATA to engage in a cross-registry data validation to improve the accuracy and completion of recipient and transplant characteristics captured in ANZIPTR. Negotiations are currently ongoing, and we hope to have an annual cross-registry exchange set up in time for the 2019 ANZIPTR annual report.

We also approached ANZOD about a cross-registry data exchange to improve the accuracy and completion of donor characteristics in ANZIPTR, and in 2017 we completed the first round of this data quality check. ANZOD records were linked to ANZIPTR deterministically using donor number. Some records were missing the donor number in ANZIPTR and hence were not linked. Remaining records were iteratively linked using the next best non-missing field, in the following order: recipient's full name, recipient's surname, recipient's given names, and all of state, transplant year, transplant month, transplant facility, and donor's sex. A final manual check was performed to correct both false positive and false negative links.

We successfully linked all 756 recipient records in ANZIPTR to their corresponding donor record in ANZOD. The number of records that were updated for each donor characteristic that we compared is presented in

Table 6.1. In future we plan to include comparisons of characteristics which are either not coded or coded inconsistently between registries, such as cause of death and donor's hospital. We found discrepancies between ANZIPTR and ANZOD in 713 records (94%). This included 208 (28%) with at least one field missing in ANZIPTR, and 611 (81%) with a conflict in at least one field. Of 377 records with conflicting donor number, 314 (83%) of these were due to missing zeroes rather than truly conflicting values. Apart from donor number, the largest number of updates were made to Epstein-Barr virus status (218 records, 29%), Cytomegalovirus status (206 records, 27%), and weight (178 records, 24%).

Table 6.1: Number of records updated in ANZIPTR

Donor characteristic	Missing (%)		Conflicting (%)		Total (%)	
Donor number [1]	0	(0)	377	(50)	377	(50)
Hospital	2	(0)	145	(19)	147	(19)
Age	28	(4)	101	(13)	129	(17)
Sex	24	(3)	19	(3)	43	(6)
Height	74	(10)	62	(8)	136	(18)
Weight	75	(10)	103	(14)	178	(24)
Blood group	51	(7)	41	(5)	92	(12)
Kidney side [2]	82	(11)	22	(3)	104	(14)
HLA matching [3]	78	(10)	104	(14)	104	(14)
Cytomegalovirus status (CMV)	60	(8)	146	(19)	206	(27)
Epstein-Barr virus status (EBV)	94	(12)	124	(16)	218	(29)
At least one of the above	208	(28)	611	(81)	713	(94)
Total records checked	756	(100)	756	(100)	756	(100)

[1] Includes 314 conflicts (83%) due to missing zeroes

[2] Only recorded for simultaneous pancreas kidney recipients

[3] Includes six fields, i.e. A1, A2, B1, B2, DR1, and DR2

Islet isolations and transplants

The quality of aggregated data available for islet isolations and transplant recipients remains poor compared to the pancreas waiting list and transplant data. Partly this is due to centre-related data capture processes, and the different data set requirements for international and national reporting. Several new characteristics and outcomes have been added to Chapter 4 in this report, as well as the introduction of a section reporting auto islet transplantation. However, there remains much room for improvement, and much enthusiasm for doing so.

Future developments

Following the success of the REDCap database for pancreas transplant referrals, discussions began in 2018 about creating a similar database for all islet transplant referrals. We are also hoping to migrate the existing pancreas transplant data from RISC to a REDCap database, which would allow integration between the pancreas waiting list and pancreas transplant databases. In addition to allowing more complex analyses in future, this would also save considerable time and effort in terms of data entry, extraction, and analysis.

Appendices

ANZIPTR Annual Report 2017

An abridged version of the ANZIPTR annual report for 2017 (including data up to the end of 2016) was published in Transplantation Direct, and can be viewed here:

https://journals.lww.com/transplantationdirect/fulltext/2017/10000/Australia_and_New_Zealand_Islets_and_Pancreas.6.aspx

The ANZIPTR annual report for 2017 should be cited as follows:

AC Webster et al., Transplantation Direct. 2017; 3(10): e211

Other abstracts and publications

There were no other abstracts or publications based on data from ANZIPTR during 2017