

ANZIPTR Report 2019

Australia and New Zealand Islet and Pancreas Transplant Registry data 1984-2018

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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Summary

Introduction

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

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

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

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Summary

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Governance structure

This report is a compilation of data provided by the four 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; National

Pancreas Transplant Unit, Westmead Hospital, NSW; South Australian/Northern Territory

Pancreas/Islet and Renal Transplant Service, Royal Adelaide Hospital, SA; 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.

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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 REDCap on 14th March 2019, for all people transplanted up to the end of 2018. Data for the islets waiting list, donors, and recipients was also extracted from FileMaker on 14th March 2019. Please note new data is added to the registry regularly, and corrections are made where previous data are missing or where errors are discovered.

Kaplan-Meier survival curves were used to illustrate the survival distributions, and these were generated using Stata software version 15 (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 transplant

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.

Islet transplant

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 Collaborative Islet Transplant Registry (CITR, https://citregistry.org/), 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)
TP-IAT Total Pancreatectomy – Islet Auto Transplant

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 870 solid organ pancreas transplants have been performed in Australia and New Zealand (ANZ), in 850 individuals from 1984-2018 (excluding islet transplants).

In 2018, 56 pancreas transplants were performed, by centre this was; Auckland (6); Monash (20); Westmead (26); and Adelaide (4). In 2018, 53 transplants were SPK while 2 were PAK and 1 was PTA.

From 2002-2018, there have been 116 Islet transplants in 68 patients (excluding auto-islets), and 11 TP-IAT procedures performed in Australia.

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)					
Activity	2016	2017	2018			
On active list at beginning of year	30	49	73			
Added to active list during the year	74	83	34			
Removed from active list during year	0	6	6			
Pancreas transplants to patients on waiting list ¹	52	48	50			
Kidney only transplants to patients on waiting list	3	3	5			
Transplants performed outside Australia/New Zealand	0	0	0			
Died while active on list	0	2	3			
On active waiting list at the end of year	49	73	43			
Died within 12 months of removal from list	0	0	0			
Under consideration but not active on list	152	185	196			
Referred but declined for pancreas transplantation	39	57	60			

¹Includes one combined kidney islet transplant performed in 2017

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

Activity	P	Patients (n)					
Activity	2016	2017	2018				
On active list at beginning of year	1	3	5				
Added to active list during the year	6	6	4				
Removed from active list during year	0	0	2				
Transplants to patients on waiting list	4	4	6				
Kidney only transplants to patients on waiting list	0	0	0				
Transplants performed outside Australia/New Zealand	0	0	0				
Died while active on list	0	0	0				
On active waiting list at the end of year	3	5	1				
Died within 12 months of removal from list	0	0	0				
Under consideration but not active on list	1	1	9				
Referred but declined for pancreas transplantation	0	0	1				

Distribution of active patients by state

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

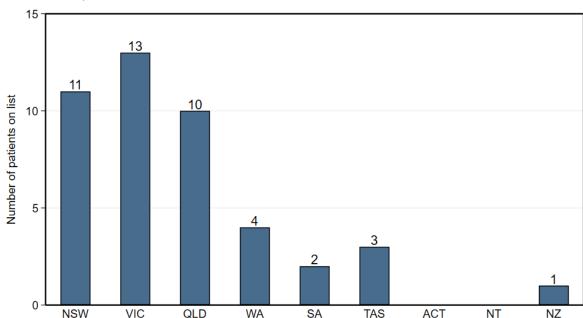


Figure 1.1: Distribution of people active on the waiting list by state or country of residence, as of December 2018

Table 1.3: Patient state of residence by Australian pancreas transplant unit for people active on the list, December 2018

State of residence, n (row %)									
Year	NSW	VIC	QLD	WA	SA	TAS	ACT	NT	Total
Westmead	d (NSW)								
2018	11 (44)	0 (0)	10 (40)	4 (16)	0 (0)	0 (0)	0 (0)	0 (0)	25
2017	23 (51)	0 (0)	14 (31)	7 (16)	1 (2)	0 (0)	0 (0)	0 (0)	45
2016	9 (45)	0 (0)	7 (35)	4 (20)	0 (0)	0 (0)	0 (0)	0 (0)	20
Monash (\	/IC)								
2018	0 (0)	13 (72)	0 (0)	0 (0)	2 (11)	3 (17)	0 (0)	0 (0)	18
2017	0 (0)	20 (74)	0 (0)	0 (0)	4 (15)	3 (11)	0 (0)	0 (0)	27
2016	0 (0)	23 (82)	0 (0)	0 (0)	3 (11)	2 (7)	0 (0)	0 (0)	28
Royal Ade	laide (SA)								
2018	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0
2017	0 (0)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	1
2016	0 (0)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	1

Table 1.4 shows 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 1.4: Patient state of residence by Australian pancreas transplant unit for people under consideration and active on the list, December 2018

	State of residence, n (row %)								
Year	NSW	VIC	QLD	WA	SA	TAS	ACT	NT	Total
Westmea	d (NSW)								
2018	49 (35)	2 (1)	41 (29)	39 (28)	7 (5)	1 (<1)	0 (0)	0 (0)	139
2017	62 (40)	1 (<1)	43 (28)	41 (26)	8 (5)	1 (<1)	0 (0)	0 (0)	156
2016	38 (34)	1 (<1)	27 (24)	36 (32)	7 (6)	1 (<1)	0 (0)	1 (<1)	111
Monash (VIC)									
2018	4 (4)	74 (74)	1 (1)	0 (0)	11 (11)	9 (9)	0 (0)	1 (1)	100
2017	1 (1)	77 (78)	1 (1)	0 (0)	10 (10)	9 (9)	0 (0)	1 (1)	99
2016	1 (1)	63 (72)	1 (1)	0 (0)	12 (14)	10 (11)	0 (0)	1 (1)	88
Royal Ade	elaide (SA)								
2018	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0
2017	0 (0)	0 (0)	0 (0)	0 (0)	3 (100)	0 (0)	0 (0)	0 (0)	3
2016	0 (0)	0 (0)	0 (0)	0 (0)	2 (100)	0 (0)	0 (0)	0 (0)	2

New referrals received over time

Table 1.5 shows the number of new referrals received by transplanting units in Australia and New Zealand over time, and by state of residence (for Australian units only).

Table 1.5: New referrals received over time by pancreas transplant unit and state of residence

	State of residence, n (row %)								
Year	NSW	VIC	QLD	WA	SA	TAS	ACT	NT	Total
Westmead	d (NSW)								
2018	3 (25)	1 (8)	6 (50)	1 (8)	1 (8)	0 (0)	0 (0)	0 (0)	12
2017	24 (59)	0 (0)	15 (37)	1 (2)	1 (2)	0 (0)	0 (0)	0 (0)	41
2016	17 (46)	0 (0)	10 (27)	8 (22)	2 (5)	0 (0)	0 (0)	0 (0)	37
Monash (\	/IC)								
2018	3 (9)	23 (70)	1 (3)	0 (0)	2 (6)	4 (12)	0 (0)	0 (0)	33
2017	0 (0)	41 (87)	0 (0)	0 (0)	4 (9)	1 (2)	0 (0)	1 (2)	47
2016	0 (0)	24 (77)	0 (0)	0 (0)	5 (16)	2 (6)	0 (0)	0 (0)	31
Royal Ade	laide (SA)								
2018	0 (0)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	1
2017	0 (0)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	1
2016	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0
Auckland (NZ)									
2018	-	-	-	-	-	-	-	-	1
2017	-	-	-	-	-	-	-	-	1
2016	-	-	-	-	-	-	-	-	5

¹ Excludes one multi-organ pancreas transplant for a Victorian resident performed at Austin Hospital in 2017

Patient characteristics for those active on the list in 2018

The following figures illustrate the distribution of other characteristics of those active on the waiting list in 2018, 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 2018

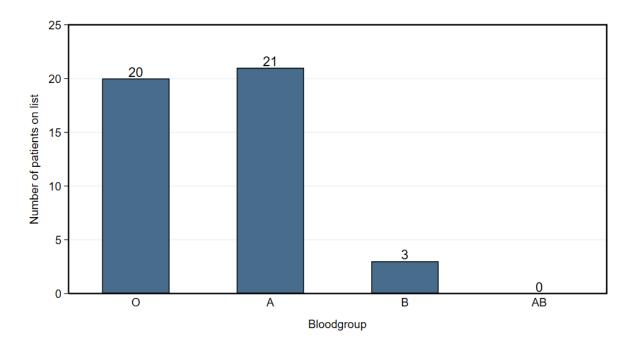
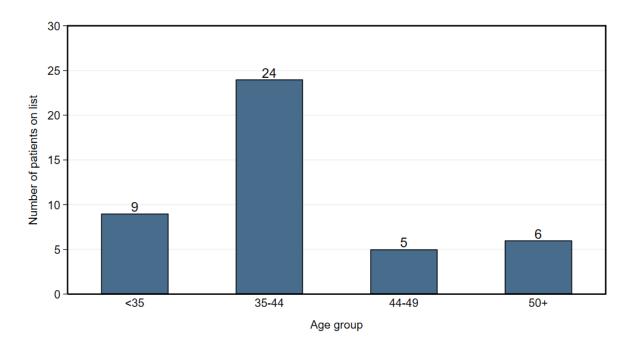


Figure 1.3: Distribution of people active on the list by their age, at December 2018



Chapter 2: Pancreas transplant recipients

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

Pancreas transplant incidence

A total of 866 solid organ pancreas transplants have been performed in Australia and New Zealand (ANZ) from 1984-2018. Transplants have been performed in Westmead (533), Monash (263), Auckland (62), and Royal Adelaide (4). In 2018 the Royal Adelaide Hospital recommenced pancreas transplantation in South Australia and the Northern Territory using an ATG based steroid free protocol. There have also been multi-organ transplants including pancreas at Royal Prince Alfred (1), Royal Melbourne Hospital (1), Queen Elizabeth Hospital (1), and Austin Hospital (1). Figure 2.1 shows pancreas transplants over time. The number of transplants has substantially increased in last decade compared to previous years.

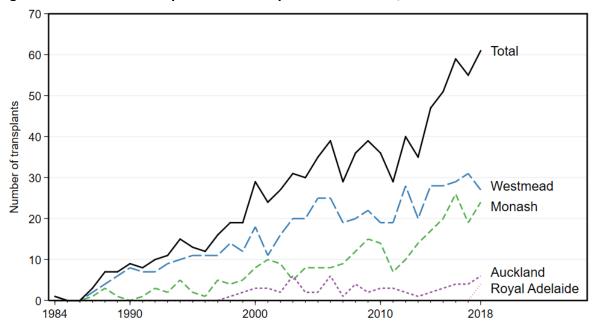


Figure 2.1: Incidence of pancreas transplants over time, 1984-2018

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

In 2018, 56 people received a pancreas transplant, by centre this was; Monash (20), Westmead (26), Royal Adelaide (4), and Auckland (6). The number of transplants in 2018 increased by 8% compared to 2017.

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 56 transplants performed in 2018, 53 were SPK, 2 were Pancreas after kidney (PAK), and 1 was 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. Its indications include management of patients with hypoglycaemic unawareness or brittle diabetes that have failed best medical therapy. On rarer occasions, a multi-organ transplant is undertaken which includes a pancreas transplant. There was one simultaneous pancreas, liver, and kidney transplant which was performed in 2005, one liver, pancreas, and intestine transplant in 2012, one liver and pancreas transplant in 2016, and one liver, kidney, pancreas, stomach and intestine transplant in 2017. 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.

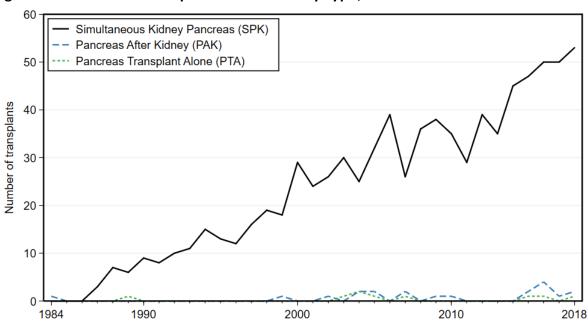


Figure 2.2: Pancreas transplants over time by type, Australia and New Zealand

Table 2.1: Pancreas transplant operations over time, by transplant hospital

Hospital and transplant type, n (row %)

Year	Westmead		Monash			Royal Adelaide	New Zealand	Total	
	SPK	PAK	PTA	SPK	PAK	PTA	All	All	All
2018	24 (43)	2 (4)	0 (0)	20 (36)	0 (0)	0 (0)	4 (7)	6 (11)	56
2017	30 (59)	0 (0)	0 (0)	16 (31)	1 (2)	0 (0)	0 (0)	4 (8)	51
2016	26 (47)	3 (5)	0 (0)	20 (36)	1 (2)	1 (2)	0 (0)	4 (7)	55
2015	27 (54)	1 (2)	0 (0)	18 (36)	1 (2)	0 (0)	0 (0)	3 (6)	50
2014	28 (62)	0 (0)	0 (0)	15 (33)	0 (0)	0 (0)	0 (0)	2 (4)	45
2013	20 (57)	0 (0)	0 (0)	14 (40)	0 (0)	0 (0)	0 (0)	1 (3)	35
2012	28 (72)	0 (0)	0 (0)	9 (23)	0 (0)	0 (0)	0 (0)	2 (5)	39
2011	19 (66)	0 (0)	0 (0)	7 (24)	0 (0)	0 (0)	0 (0)	3 (10)	29
2010	19 (53)	0 (0)	0 (0)	14 (39)	0 (0)	0 (0)	0 (0)	3 (8)	36
2009	22 (56)	0 (0)	0 (0)	14 (36)	1 (3)	0 (0)	0 (0)	2 (5)	39
2008	20 (56)	0 (0)	0 (0)	12 (33)	0 (0)	0 (0)	0 (0)	4 (11)	36
2007	16 (55)	2 (7)	1 (3)	9 (31)	0 (0)	0 (0)	0 (0)	1 (3)	29
2006	25 (64)	0 (0)	0 (0)	8 (21)	0 (0)	0 (0)	0 (0)	6 (15)	39
2005	21 (62)	2 (6)	1 (3)	8 (24)	0 (0)	0 (0)	0 (0)	2 (6)	34
2004	15 (52)	2 (7)	2 (7)	8 (28)	0 (0)	0 (0)	0 (0)	2 (7)	29
2003	19 (61)	0 (0)	1 (3)	5 (16)	0 (0)	0 (0)	0 (0)	6 (19)	31
2002	15 (56)	1 (4)	0 (0)	9 (33)	0 (0)	0 (0)	0 (0)	2 (7)	27
2001	11 (46)	0 (0)	0 (0)	10 (42)	0 (0)	0 (0)	0 (0)	3 (13)	24
2000	18 (62)	0 (0)	0 (0)	8 (28)	0 (0)	0 (0)	0 (0)	3 (10)	29
1999	11 (58)	1 (5)	0 (0)	5 (26)	0 (0)	0 (0)	0 (0)	2 (11)	19
1998	14 (74)	0 (0)	0 (0)	4 (21)	0 (0)	0 (0)	0 (0)	1 (5)	19
1997	11 (69)	0 (0)	0 (0)	5 (31)	0 (0)	0 (0)	0 (0)	0 (0)	16
1996	11 (92)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	12
1995	11 (85)	0 (0)	0 (0)	2 (15)	0 (0)	0 (0)	0 (0)	0 (0)	13
1994	10 (67)	0 (0)	0 (0)	5 (33)	0 (0)	0 (0)	0 (0)	0 (0)	15
1993	9 (82)	0 (0)	0 (0)	2 (18)	0 (0)	0 (0)	0 (0)	0 (0)	11
1992	7 (70)	0 (0)	0 (0)	3 (30)	0 (0)	0 (0)	0 (0)	0 (0)	10
1991	7 (88)	0 (0)	0 (0)	1 (13)	0 (0)	0 (0)	0 (0)	0 (0)	8
1990	8 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	8
1989	5 (71)	0 (0)	1 (14)	1 (14)	0 (0)	0 (0)	0 (0)	0 (0)	7
1988	4 (67)	0 (0)	0 (0)	2 (33)	0 (0)	0 (0)	0 (0)	0 (0)	6
1987	2 (67)	0 (0)	0 (0)	1 (33)	0 (0)	0 (0)	0 (0)	0 (0)	3
1986	0 (0)	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 (0)	0
1984	0 (0)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	1
Total	513 (60)	14 (2)	6 (<1)	256 (30)	5 (<1)	1 (<1)	4 (<1)	62 (7)	861

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

The above table excludes the four transplants performed in Australia outside of Westmead, Monash, or Royal Adelaide in 1988, 1990, 2005, and 2017.

The above table also excludes one combined liver-pancreas transplant performed at Monash in 2016.

Patients transplanted by state

The states of origin of the people receiving pancreas transplants at each transplant unit in Australia over time are shown in Table 2.2.

Table 2.2: Distribution of state of residence of people receiving pancreas transplants over time

		State of residence, n (row %)							
Year	NSW	VIC	QLD	WA	SA	TAS	ACT	NT	Total
Westmead	Westmead (NSW)								
2018	15 (58)	0 (0)	6 (23)	3 (12)	2 (8)	0 (0)	0 (0)	0 (0)	26
2017	14 (47)	0 (0)	11 (37)	2 (7)	1 (3)	0 (0)	2 (7)	0 (0)	30
2016	12 (41)	0 (0)	10 (34)	5 (17)	2 (7)	0 (0)	0 (0)	0 (0)	29
Monash (VI	Monash (VIC)								
2018	0 (0)	17 (85)	0 (0)	0 (0)	2 (10)	1 (5)	0 (0)	0 (0)	20
2017	0 (0)	14 (82)	0 (0)	0 (0)	2 (12)	1 (6)	0 (0)	0 (0)	17
2016	0 (0)	16 (70)	0 (0)	0 (0)	6 (26)	1 (4)	0 (0)	0 (0)	23
Royal Adela	aide (SA)								
2018	0 (0)	0 (0)	0 (0)	0 (0)	4 (100)	0 (0)	0 (0)	0 (0)	4
2017	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0
2016	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0
Auckland (N	NZ)								
2018	-	-	-	-	-	-	-	-	6
2017	-	-	-	-	-	-	-	-	4
2016	-	-	-	-	-	-	-	-	4

Demographics of new pancreas transplant recipients

The characteristics of pancreas transplant recipients in 2018 and in previous years are shown in Table 2.3. The primary diagnosis causing end stage kidney disease of recipients during 2018 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 2018.

Patients, n (column %)	2018	1984-2017	Total
Age category			
Median (IQR)	40 (35, 44)	39 (33, 44)	39 (33, 44)
0-34	10 (17)	262 (32)	272 (31)
35-44	33 (58)	360 (44)	393 (45)
45-50	9 (16)	133 (16)	142 (16)
50+	4 (7)	55 (6)	59 (6)
Sex			
Female	26 (46)	377 (46)	403 (46)
Male	30 (53)	433 (53)	463 (53)
Cause of end stage kidney disease			
Diabetes type 1	53 (94)	792 (97)	845 (97)
Diabetes type 2	0 (0)	1 (<1)	1 (<1)
Haemolytic uraemic syndrome	0 (0)	1 (<1)	1 (<1)
Interstitial nephritis	0 (0)	1 (<1)	1 (<1)
Wegener's granulomatosis	0 (0)	1 (<1)	1 (<1)
No kidney disease ¹	3 (5)	14 (1)	17 (1)
Ethnicity ²			
Indigenous Australian	0 (0)	2 (<1)	2 (<1)
Maori	0 (0)	5 (<1)	5 (<1)
Pacific islander	4 (7)	5 (<1)	9 (1)
White	49 (87)	772 (95)	821 (94)
North Asian	0 (0)	3 (<1)	3 (<1)
South-East Asian	0 (0)	0 (0)	0 (0)
Southern and Central Asian	3 (5)	14 (1)	17 (1)
North African and Middle Eastern	0 (0)	9 (1)	9 (1)
Blood group			
0	27 (48)	379 (46)	406 (46)
A	21 (37)	318 (39)	339 (39)
В	4 (7)	76 (9)	80 (9)
AB	4 (7)	37 (4)	41 (4)
Total	56	810	866

¹ Ethnicity classified according to the Australian Bureau of Statistics standard classification, 2nd Edition; http://www.abs.gov.au/AUSSTATS/abs@.nsf/DetailsPage/1249.02011

² Includes 11 pancreas transplants after kidney (PAK) and 6 pancreas transplants alone (PTA)

The type of pancreas transplants and the types of donors for transplants performed in 2018 is presented in Table 2.4, stratified by country and sex.

Table 2.4: Transplant and donor types in 2018 by country and sex

	Australia		New Zealand		Overall		
	Female	Male	Female	Male	Female	Male	Total
Pancreas alone	2	1	0	0	2	1	3
DBD	2	1	0	0	2	1	3
DCD	0	0	0	0	0	0	0
SPK	15	32	2	4	17	36	53
DBD	14	31	2	4	16	35	51
DCD	1	1	0	0	1	1	2

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

Balance of donor and recipient characteristics in 2018

Cross tabulations of donor and recipient blood group and gender for people transplanted in 2018 are displayed in Table 2.5 and Table 2.6. These distributions remain similar to previous years.

Table 2.5: Cross tabulation of recipient and donor blood groups for 2018

Desirient blood group	Donor blood group, n (row %)					
Recipient blood group	0	Α	В	AB	Total	
0	27 (100)	0 (0)	0 (0)	0 (0)	27	
A	1 (4)	20 (95)	0 (0)	0 (0)	21	
В	0 (0)	0 (0)	4 (100)	0 (0)	4	
AB	0 (0)	2 (50)	0 (0)	2 (50)	4	
Total	28 (50)	22 (39)	4 (7)	2 (3)	56	

Table 2.6: Cross tabulation of recipient and donor sex for 2018

Paciniant cov	Donor sex	Total	
Recipient sex	Female	Male	IOtal
Female	8 (30)	18 (69)	26
Male	11 (36)	19 (63)	30
Total	19 (33)	37 (66)	56

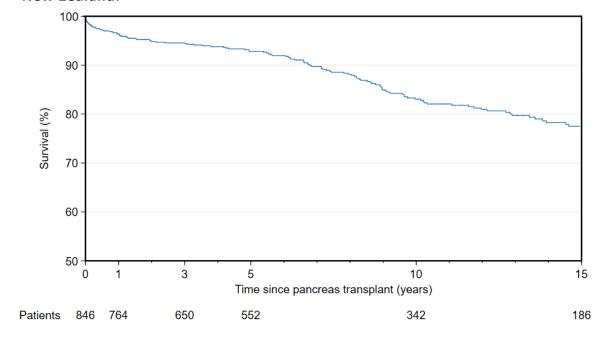
McNemar's test for difference p=0.2

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 846 patients, 20 of whom have received a second pancreas transplant, for a total of 866 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.

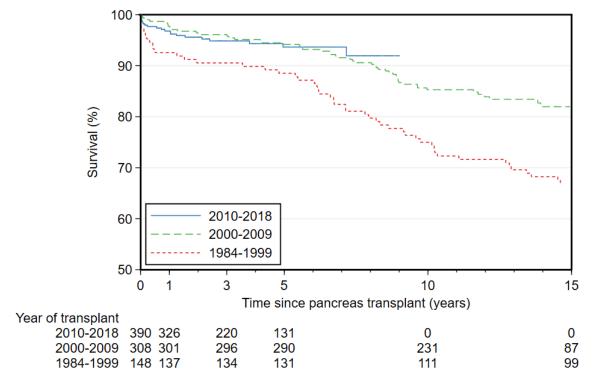
Figure 2.3 shows overall survival following pancreas transplant. There were 7,853 years of follow-up, and 146 people died in that time. Survival at 1 year was 96.4%, at 5 years 92.8%, at 10 years 83.1% and at 15 years 77.5%.

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<0.001). Survival at 1 year for people transplanted before 2000 was 92.6%; in recent years this has risen to 96.8%. Survival at 5 years was 88.5% for those transplanted before 2000, where for those transplanted in 2010 or later, 5-year survival was 93.7%.





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=0.02). Survival at 1 year for recipients aged <35 years was 97.0%, and for those aged 35-44 was 96.5%, whereas for those aged 45-49 was 94.8% and for those 50 or older was 96.6%. Survival at 5 years for those aged <35 years was 92.5%, and for those aged 35-44 was 94.0%, whereas for those aged 45-49 was 90.6% and for those 50 or older was 92.9%. The greater survival for the 50 years and older group may be because these recipients are a more highly selected population.

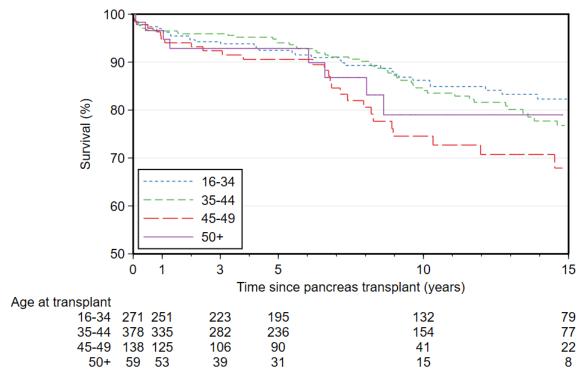


Figure 2.5: Patient survival by age at transplantation

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 at death with a functioning transplant. For pancreas transplant survival we included all pancreas transplants undertaken, including those who had received a pancreas transplant twice (20 patients). At the time of this report, we had survival records for 866 pancreas transplants.

Figure 2.6 shows pancreas transplant survival censored at death. Over 6,747 years of follow-up, there were 142 pancreas transplant failures (excluding people who died with a functioning transplant). Overall, 1-year pancreas transplant survival was 90.4%, 5-year survival 85.8%, and 10-year survival 82.3%.

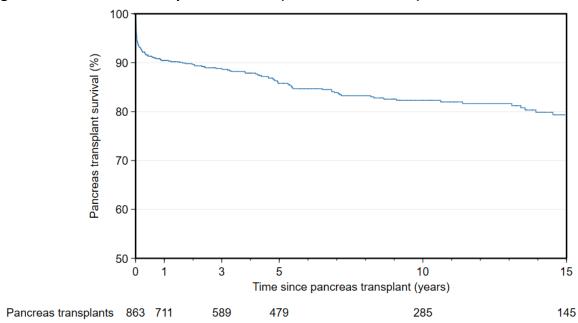
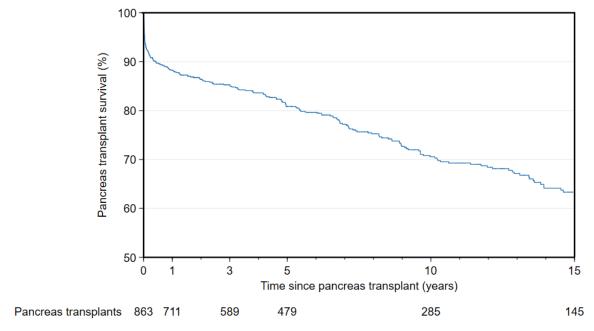


Figure 2.6: Pancreas transplant survival (censored at death)

Figure 2.7 shows pancreas transplant survival including death with a functioning pancreas. Over the same observation time there were 252 recipients who either died or experienced pancreas transplant failure. Survival at 1, 5 and 10 years was 88.3%, 80.8% and 70.6% respectively.





Survival of pancreas transplants has changed over time, as shown in Figure 2.8. Survival improved markedly over time (p=0.007). For those transplanted prior to 2000, 1-year pancreas transplant survival was 82.3%, and 5-year survival 76.6%. For those transplanted in 2010 or later, 1-year survival was 93.5% and 5-year survival 88.0%.

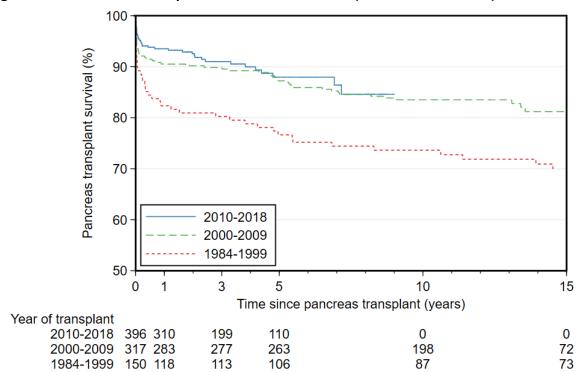


Figure 2.8: Pancreas transplant survival over time (censored at death)

Pancreas transplant 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=0.6). Pancreas transplant survival at 1 year was 91.0% for transplants where the donor was underweight/normal BMI, 90.1% for transplants where the donor was overweight, and 86.1% where the donor was obese.

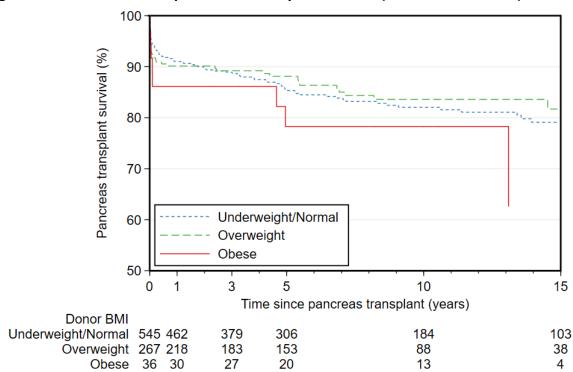


Figure 2.9: Pancreas transplant survival by donor BMI (censored at death)

Pancreas transplant survival by donor age is presented in Figure 2.10. The survival curves are poorer for donors aged 35-44 compared with those 45 and older, or younger donors (p=0.03). 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. Pancreas transplant survival at 1 year was 92.5% for transplants from donors aged 0-24 years, 90.1% for donors aged 25-34 years, 85.9% for donors aged 35-44 years, and 93.8% for donors aged 45+ years.

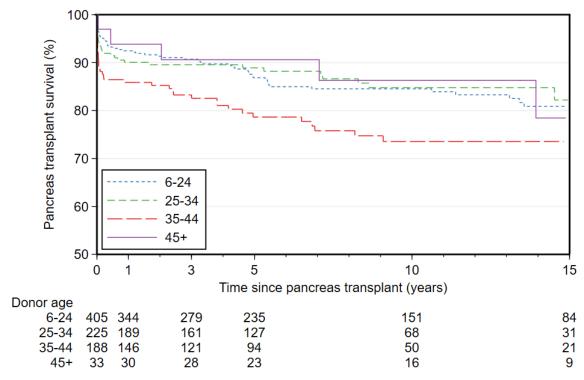


Figure 2.10: Pancreas transplant survival by donor age (censored at death)

Pancreas transplant survival at 1 year and 5 years post-transplant, censored at death and stratified by country and era of transplantation is presented in Table 2.7.

Table 2.7: Pancreas transplant survival censored at death, by country and era

Australia					New Zealand				
	1-	1-year 5-yea		year	1	-year		5-year	
Year of transplant	Ν	%	N	%	Ν	%	Ν	%	
2010-2015	197	91.3%	104	85.3%	14	92.9%	8	92.9%	
2011-2016	216	91.6%	76	85.3%	15	93.3%	7	93.3%	
2012-2017	237	92.6%	55	86.5%	16	93.8%	4	93.8%	
2013-2018	205	93.6%	27	88.6%	14	95.0%	2	95.0%	

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 2.8). The below numbers exclude people still alive, but whose pancreas transplant has failed. The number of functioning transplants is remaining steady over time, possibly because recipients of early transplants are ageing (with increased deaths and pancreas transplant failures) which is being offset by the increase in new transplants performed.

Table 2.8: People alive with a functioning pancreas transplant in Australia and New Zealand by year and residence, at year's end

	22, 32, 32				
State/country of residence	2014	2015	2016	2017	2018
New South Wales	159	156	153	149	148
Victoria	179	177	177	174	173
Queensland	124	119	116	112	112
Western Australia	37	35	33	30	29
South Australia	50	49	48	48	47
Tasmania	26	25	25	25	25
Australian Capital Territory	14	14	13	12	12
Northern Territory	4	4	4	4	4
New Zealand	50	48	48	48	48
Total	643	627	617	602	598

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 at death with a functioning graft. For kidney transplant survival we included only SPK transplants and excluded PAK transplant recipients. We had survival records for 835 SPK transplants.

Figure 2.11 shows kidney survival censored at death. Over 7,069 years of observation, there were 88 kidney transplant failures (excluding people who died with a functioning kidney transplant). Overall, 1-year kidney transplant survival was 97.0%, 5-year survival 94.0%, and 10-year survival 88.7%.

Figure 2.11: Kidney transplant survival for people receiving SPK transplants (censored at death)

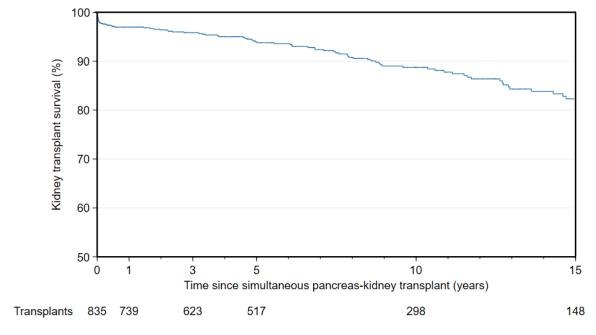
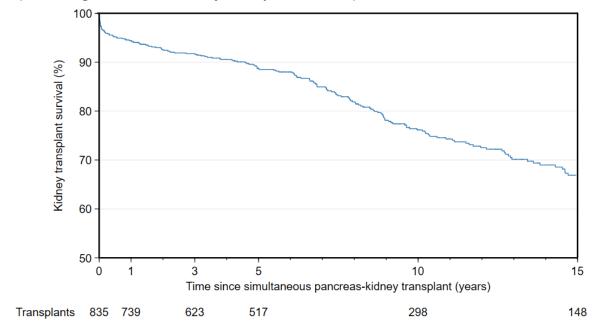


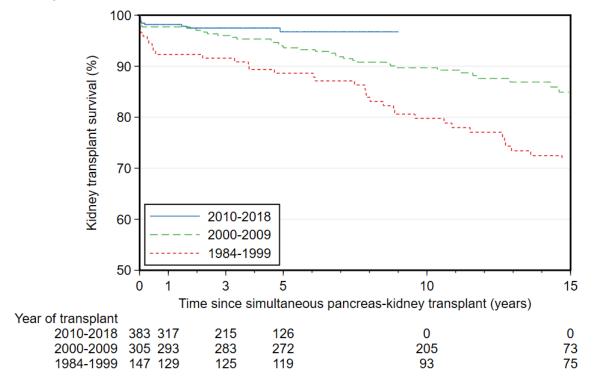
Figure 2.12 shows kidney survival including death with a functioning kidney. Over the same observation time there were 196 recipients who either died with kidney transplant function or experienced kidney transplant failure. Kidney transplant survival at 1, 5 and 10 years was 94.4%, 88.7% and 76.2% respectively.

Figure 2.12: Kidney transplant survival for people receiving SPK transplants (including death as a kidney transplant failure)



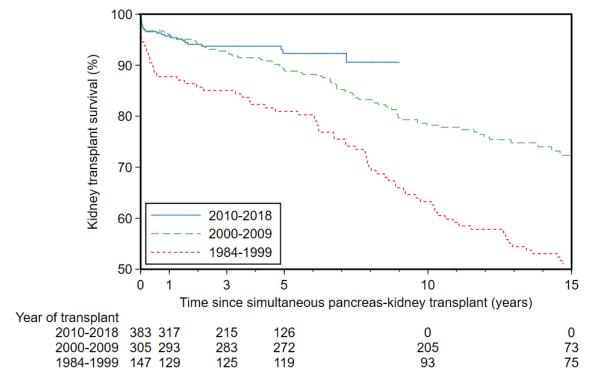
Kidney transplant survival improved over time, with longer survival for those transplanted in more recent years (p<0.001). For those transplanted before 2000, kidney transplant survival was 92.3% at 1 year and 88.6% at 5 years but was 98.2% at 1 year and 96.7% at 5 years for those transplanted in 2010 or later (Figure 2.13).

Figure 2.13: Kidney transplant survival for SPK recipients over time (censored at death)



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 95.7% at 1 year and 92.3% at 5 years for those transplanted in 2010 or later (Figure 2.14).

Figure 2.14: Kidney transplant survival for SPK recipients over time (including death as a kidney transplant failure)



Pancreas transplant operative data

Characteristics of the pancreas transplant operations for 2018, previous years, and overall are shown in Table 2.9 below.

Table 2.9: Descriptive characteristics of pancreas transplant operations

	2018	1984-2017	Total
Pancreas transplant			
Total pancreas transplants	56	810	866
Cold ischaemic time (hours)			
Patients (%)	26 (46)	673 (83)	699 (81)
Mean (SD)	7.1 (2.3)	10.7 (3.5)	10.5 (3.5)
Median (IQR)	6 (6, 8)	11 (8, 13)	11 (8, 13)
Anastomosis time (minutes)			
Patients (%)	5 (9)	684 (84)	689 (80)
Mean (SD)	27.0 (3.9)	29.7 (8.0)	29.7 (8.0)
Median (IQR)	29 (25, 30)	30 (25, 34)	30 (25, 34)
Exocrine drainage			
Enteric, n (%)	54 (96)	575 (71)	629 (73)
Bladder, n (%)	0 (0)	164 (20)	164 (19)
Not reported, n (%)	2 (4)	71 (9)	73 (8)
Kidney transplant			
Total SPK transplants	53	782	835
Cold ischaemic time (hours)			
Patients (%)	24 (43)	650 (80)	674 (78)
Mean (SD)	6.8 (2.0)	10.7 (3.4)	10.5 (3.5)
Median (IQR)	6 (6, 7)	11 (8, 13)	11 (8, 13)
Anastomosis time (minutes)			
Patients (%)	4 (7)	659 (81)	663 (77)
Mean (SD)	26.5 (4.4)	29.8 (8.0)	29.7 (8.0)
Median (IQR)	27 (23, 30)	30 (25, 34)	30 (25, 34)
Kidney donor arteries			
None, n (%)	0 (0)	2 (<1)	2 (<1)
One, n (%)	23 (41)	586 (72)	609 (70)
Two, n (%)	1 (2)	67 (8)	68 (8)
Three, n (%)	0 (0)	4 (<1)	4 (<1)
Not reported, n (%)	29 (52)	123 (15)	152 (18)

SPK, simultaneous pancreas-kidney

To investigate how much the total cold ischaemic time varied dependant on the donor state, and distance travelled to the transplanting centre, Table 2.10 displays a cross tabulation of donor state of origin with transplanting centre.

Table 2.10: Comparison of cold ischaemic time of pancreas transplants by donor state, for Australian pancreas transplants 2018

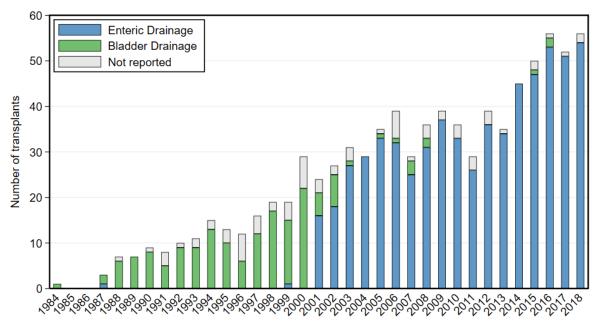
	Cold ischaemic time in hours								
Donor state	We	stmead (NSW)	Mon	ash (VIC)	Royal A	Royal Adelaide (SA)			
	Ν	Mean (SD)	Ν	Mean (SD)	N	Mean (SD)			
New South Wales	1	6	1	5	0	-			
Victoria	0	-	16	6.6 (1.2)	0	-			
Queensland	2	13.2 (-)	0	-	0	-			
Western Australia	0	-	1	4.1	3	7 (1.7)			
South Australia	0	-	1	5.5	0	-			
Tasmania	0	-	0	-	0	-			
Australian Capital Territory	0	-	0	-	0	-			
Northern Territory	0	-	0	-	1	10 (-)			
Total	3	10.7 (4.1)	19	6.3 (1.3)	4	7.8 (2.1)			

Note: There is a lot of missing data for cold ischaemic times, hence data in this table may not be representative of all pancreas transplants

Surgical technique

Exocrine drainage of the pancreas transplant 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.

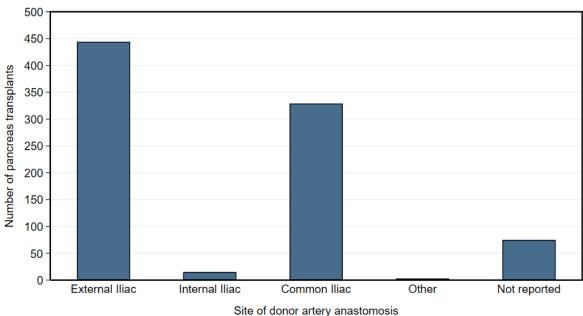
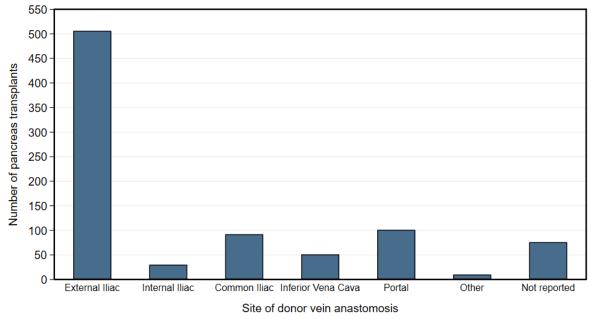


Figure 2.16: Site of donor artery anastomosis onto recipient vessel





The immunological matching of donor-recipient pairs is shown in Table 2.11, and the cytomegalovirus (CMV) and Epstein-Barr virus (EBV) matching is illustrated in Table 2.12.

Table 2.11: Immunological cross-matching of donor recipient pairs

	Donor-recipient pairs, n (column %)			
	Current	Peak		
Crossmatch				
T-cell Positive	0 (0)	2 (<1)		
B-cell Positive	3 (<1)	4 (<1)		
T and B cell Negative	729 (84)	714 (82)		
DTT Negative	1 (<1)	1 (<1)		
None recorded	0 (0)	1 (<1)		
Not reported	133 (15)	144 (17)		
Panel Reactive Antibodies (%)				
0-49	120 (14)	118 (14)		
50+	1 (<1)	9 (1)		
Not reported	745 (86)	739 (85)		

Table 2.12: Infectious disease serology cross-tabulation of donor-recipient pairs

Positiont socials at	Donor serology, n (column %)						
Recipient serology	Positive	Negative	Not reported				
Cytomegalovirus (CMV)							
Positive	88 (17)	43 (13)	3 (9)				
Negative	10 (2)	6 (2)	0 (0)				
Not reported	413 (81)	271 (85)	32 (91)				
Epstein-Barr virus (EBV)							
Positive	109 (22)	17 (21)	21 (8)				
Negative	2 (<1)	0 (0)	1 (<1)				
Not reported	395 (78)	64 (79)	257 (92)				

Chapter 3: Pancreas donors

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

This chapter gives an overview of donors in 2018 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

	0	onors, n (column	%)
	2018	1984-2017	Total
Total (row %)	56 (100)	810 (100)	866 (100)
Age category			
0-24	27 (48)	385 (48)	412 (48)
25-34	13 (23)	213 (26)	226 (26)
35-44	15 (27)	177 (22)	192 (22)
45+	1 (2)	32 (4)	33 (4)
Not reported	0 (0)	3 (<1)	3 (<1)
Sex			
Female	19 (34)	487 (60)	506 (58)
Male	37 (66)	322 (40)	359 (41)
Not reported	0 (0)	1 (<1)	1 (<1)
BMI (kg/m2)			
Underweight/Normal (<24.9)	27 (48)	521 (64)	548 (63)
Overweight (25-29.9)	16 (29)	251 (31)	267 (31)
Obese (30+)	1 (2)	35 (4)	36 (4)
Not reported	12 (21)	3 (<1)	15 (2)
Donor type			
Brain death (DBD)	54 (96)	800 (99)	854 (99)
Circulatory death (DCD)	2 (4)	10 (1)	12 (1)
Donor mode of death			
Cerebral hypoxia/ischaemia	18 (32)	83 (10)	101 (12)
Cerebral infarct	2 (4)	15 (2)	17 (2)
Intracranial haemorrhage	15 (27)	216 (27)	231 (27)
Non-neurological condition	5 (9)	189 (23)	194 (22)
Other neurological condition	1 (2)	17 (2)	18 (2)
Traumatic brain injury	14 (25)	288 (36)	302 (35)
Not reported	1 (2)	2 (<1)	3 (<1)
Alcohol consumption			
Never	11 (20)	642 (79)	653 (75)
Former	0 (0)	4 (<1)	4 (<1)
Current	13 (23)	36 (4)	49 (6)
Not reported	32 (57)	128 (16)	160 (18)
Smoking history			
Never	10 (18)	509 (63)	519 (60)
Former	1 (2)	33 (4)	34 (4)
Current	17 (30)	191 (24)	208 (24)
Not reported	28 (50)	77 (10)	105 (12)
Donor's blood group			
0	28 (50)	412 (51)	440 (51)
Α	22 (39)	299 (37)	321 (37)
В	4 (7)	79 (10)	83 (10)
АВ	2 (4)	19 (2)	21 (2)
Not reported	0 (0)	1 (<1)	1 (<1)

	[Donors, n (column %)					
	2018	1984-2017	Total				
Kidney biopsy							
Performed	11 (20)	176 (22)	187 (22)				
Not performed	26 (46)	626 (77)	652 (75)				
Not reported	19 (34)	8 (<1)	27 (3)				
Cytomegalovirus (CMV)							
Positive	16 (29)	495 (61)	511 (59)				
Negative	13 (23)	307 (38)	320 (37)				
Not reported	27 (48)	8 (<1)	35 (4)				
Epstein-Barr virus (EBV)							
Positive	17 (30)	489 (60)	506 (58)				
Negative	4 (7)	77 (10)	81 (9)				
Not reported	35 (63)	244 (30)	279 (32)				

DBD, donor after brain death; DCD, donor after circulatory death

The distribution of donor states of origin by transplanting unit for Australian pancreas donors is shown in Table 3.2.

Table 3.2: Distribution of state of residence of pancreas donors in Australia over time, by national pancreas transplant unit

Ctata			Donors, n (column %)		
State	2018	2017	2016	2015	2014	2013
Westmead (NSW)						
NSW	13 (50)	14 (47)	10 (34)	15 (54)	10 (36)	7 (35)
VIC	1 (4)	0 (0)	1 (3)	1 (4)	2 (7)	0 (0)
QLD	7 (27)	4 (13)	10 (34)	4 (14)	3 (11)	2 (10)
WA	2 (8)	7 (23)	5 (17)	4 (14)	3 (11)	4 (20)
SA	0 (0)	1 (3)	0 (0)	3 (11)	5 (18)	5 (25)
TAS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
ACT	3 (12)	3 (10)	3 (10)	1 (4)	5 (18)	2 (10)
NT	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)
Monash (VIC)						
NSW	1 (5)	0 (0)	0 (0)	0 (0)	1 (7)	7 (50)
VIC	17 (85)	15 (88)	16 (70)	16 (84)	11 (73)	6 (43)
QLD	0 (0)	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)
WA	1 (5)	1 (6)	3 (13)	0 (0)	1 (7)	0 (0)
SA	1 (5)	0 (0)	2 (9)	3 (16)	0 (0)	0 (0)
TAS	0 (0)	0 (0)	1 (4)	0 (0)	2 (13)	1 (7)
ACT	0 (0)	0 (0)	1 (4)	0 (0)	0 (0)	0 (0)
NT	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Chaha	Donors, n (column %)									
State	2018	2017	2016	2015	2014	2013				
Royal Adelaide (SA)										
NSW	0 (0)	0 -	0 -	0 -	0 -	0 -				
VIC	0 (0)	0 -	0 -	0 -	0 -	0 -				
QLD	0 (0)	0 -	0 -	0 -	0 -	0 -				
WA	0 (0)	0 -	0 -	0 -	0 -	0 -				
SA	3 (75)	0 -	0 -	0 -	0 -	0 -				
TAS	0 (0)	0 -	0 -	0 -	0 -	0 -				
ACT	0 (0)	0 -	0 -	0 -	0 -	0 -				
NT	1 (25)	0 -	0 -	0 -	0 -	0 -				

Donor and recipient state/territory

Table 3.3 shows 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 2018, and from inception of the pancreas program. Note, these tables include Australian donors and recipients only.

Table 3.3: Number of pancreas transplants by donor and recipient state of residence in Australia for 2018 and all years

Posiniont state	Donor state (number of transplants)									Total
Recipient state	NSW	VIC	QLD	WA	SA	TAS	ACT	NT	Not reported	TOTAL
2018 only	14	18	7	3	4	0	3	1	0	50
NSW	10	0	3	0	0	0	2	0	0	15
VIC	1	14	0	1	1	0	0	0	0	17
QLD	1	0	4	1	0	0	0	0	0	6
WA	1	1	0	1	0	0	0	0	0	3
SA	1	2	0	0	3	0	1	1	0	8
TAS	0	1	0	0	0	0	0	0	0	1
ACT	0	0	0	0	0	0	0	0	0	0
NT	0	0	0	0	0	0	0	0	0	0
All years (1984-2018)	304	236	73	54	70	23	37	2	3	802
NSW	144	9	26	16	21	4	18	0	0	238
VIC	22	183	1	5	7	16	2	0	3	239
QLD	68	9	27	15	22	0	10	1	0	152
WA	20	4	12	10	5	1	2	0	0	54
SA	17	19	3	5	11	1	5	1	0	62
TAS	16	10	1	0	1	1	0	0	0	29
ACT	16	1	3	1	2	0	0	0	0	23
NT	1	0	0	2	1	0	0	0	0	4
Not reported	0	1	0	0	0	0	0	0	0	1

Chapter 4: Islet cell transplants

Authors: Patricia Anderson, Natasha Rogers, Henry Pleass, 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 2018 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 2018, while Table 4.3 shows the islet waiting list activity over time.

Table 4.1: Referrals for allogenic islet transplant during 2018 by state of residence and transplant centre

State of residence	Westmead	St. Vincent's	Royal Adelaide	Total
New South Wales	9	0	0	9
Victoria	0	14	0	14
Queensland	3	0	0	3
Western Australia	1	0	0	1
South Australia	0	0	2	2
Tasmania	0	0	0	0
Australian Capital Territory	0	0	0	0
Northern Territory	0	0	0	0

Table 4.2: Patients accepted onto a waiting list for an allogenic islet transplant during 2018 by state of residence and transplant centre

State of residence	Westmead	St. Vincent's	Royal Adelaide	Total
New South Wales	9	0	0	9
Victoria	0	5	0	5
Queensland	3	0	0	3
Western Australia	1	0	0	1
South Australia	0	0	2	2
Tasmania	0	0	0	0
Australian Capital Territory	0	0	0	0
Northern Territory	0	0	0	0

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

	Patients (n)			
	2018	2017	2016	2015
Waiting list activity				
Active list at beginning of year	14	8	3	6
Added to active list during the year	14	17	16	17
First transplant	10	11	9	13
Second transplant	6	4	8	7
Third transplant	0	3	0	1
Removed from active list during year	10	10	10	19
First transplant	8	5	4	16
Second transplant	6	4	8	7
Third transplant	0	3	0	1
Death while active on list	0	0	0	0
Death within 12 months of removal from list	0	0	0	0
Active waiting list at the end of year	16	14	8	3
Transplants to waiting list				
Recipients	10	10	10	19
Transplants	14	12	12	24
Under consideration but not active on list	10	1	1	1
Referred but declined for islet transplantation	0	0	0	0

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	2018	2002-2017	Total
Westmead (NSW)			
Pancreata donations discarded before isolation	0	9	9
Islet isolations			
Islet isolations used for transplant	6	48	54
Islet isolations discarded	5	176	181
Islet recipients	5	28	30
St. Vincent's (VIC)			
Pancreata donations discarded before isolation	2	57	59
Islet isolations			
Islet isolations used for transplant	8	44	52
Islet isolations discarded	8	146	154
Islet recipients	6	24	30

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). Donor characteristics are influenced in part by the Australian donor pancreas allocation policy which allocates pancreata for both pancreatic islet isolation and for whole pancreas transplantation. This policy is available at https://www.tsanz.com.au/organallocationguidelines/index.asp

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

		Donors (n)			
	2018	2002 - 2017	Total		
Total	11	250	261		
Age					
Mean (SD)	47.5 (9.1)	45.3 (12.8)	45.4 (12.7)		
0-24	0	23	23		
25-34	2	31	33		
35-44	1	47	48		
45+	8	148	156		
Not reported	0	1	1		
Sex					
Female	5	100	105		
Male	6	147	153		
BMI kg/m ²					
Mean (SD)	30.1 (6.0)	28.7 (6.5)	28.8 (6.5)		
Underweight (<18.5)	0	3	3		
Normal weight (18.5-24)	4	81	85		
Overweight (25-29)	2	83	85		
Obese (30+)	5	82	87		
Not reported	0	1	1		
State of residence					
New South Wales	5	116	121		
Victoria	1	46	47		
Queensland	2	34	36		
Western Australia	0	34	34		
South Australia	1	12	13		
Tasmania	0	5	5		
Australian Capital Territory	2	1	3		
Northern Territory	0	0	0		
Not reported	0	2	2		
Donor type					
Brain dead (DBD)	0	242	242		
Circulatory death (DCD)	0	8	8		

Donor mode of death			
Cerebral hypoxia/ischaemia	3	23	26
Cerebral infarct	2	11	13
Intracranial haemorrhage	5	116	121
Non-neurological condition	1	26	27
Other neurological condition	0	3	3
Traumatic brain injury	0	23	23
Not reported	0	40	40
Days ventilated prior to donation			
Mean (SD)	3.6 (2.3)	2.9 (2.5)	2.9 (2.5)
Alcohol consumption			
Never	5	12	17
Former	0	2	2
Current	1	132	133
Not reported	5	104	109
Smoking history			
Never	5	46	51
Former	0	3	3
Current	6	130	136
Not reported	0	71	71
Cultural and ethnic group			
Indigenous Australian or Torres Strait Islander	0	1	1
Maori or Pacific Islander	0	0	0
White	10	202	212
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
Not reported	0	40	40
Blood group			
0	6	124	130
Α	5	100	105
В	0	17	17
AB	0	8	8
Not reported	0	1	1
CMV serology			
Negative	6	110	116
Positive	5	80	85
Not reported	0	20	20

Table 4.6: Donor characteristics for allogenic islet isolations performed in St

Vincent's Hospital (VIC)

		Donors (n)	
	2018	2002 - 2017	Total
Total	18	139	157
Age			
Mean (SD)	52.6 (10.4)	47.6 (13.3)	48.2 (13.1)
0-24	0	10	10
25-34	1	14	15
35-44	3	26	29
45+	14	89	103
Sex			
Female	10	68	78
Male	8	71	79
BMI kg/m²			
Mean (SD)	26.2 (3.3)	29.0 (6.5)	28.6 (6.3)
Underweight (<18.5)	0	0	0
Normal weight (18.5-24)	9	42	51
Overweight (25-29)	6	47	53
Obese (30+)	3	50	53
State of residence			
New South Wales	4	9	13
Victoria	7	74	81
Queensland	0	1	1
Western Australia	2	3	5
South Australia	2	37	39
Tasmania	2	8	10
Australian Capital Territory	1	1	2
Northern Territory	0	5	5
Not reported	0	1	1
Donor type			
Brain dead (DBD)	2	7	9
Circulatory death (DCD)	16	132	148
Donor mode of death			
Cerebral hypoxia/ischaemia	5	27	32
Cerebral infarct	1	10	11
Intracranial haemorrhage	9	50	59
Non-neurological condition	0	7	7
Other neurological condition	0	9	9
Traumatic brain injury	2	12	14
Not reported	1	24	25
Days ventilated prior to donation			
Mean (SD)	3.2 (1.7)	3.0 (1.9)	3.0 (1.9)

		Donors (n)	
	2018	2002 - 2017	Total
Alcohol consumption			
Never	3	23	26
Former	0	3	3
Current	15	76	91
Not reported	0	37	37
Smoking history			
Never	8	41	49
Former	2	16	18
Current	8	44	52
Not reported	0	38	38
Cultural and ethnic group			
Indigenous Australian or Torres Strait Islander	0	0	0
Maori or Pacific Islander	0	1	1
White	18	47	65
North East Asian (Chinese)	0	0	0
South East Asian	0	1	1
South and Central Asian (Indian)	0	0	0
Middle Eastern or North African	0	0	0
Other	0	1	1
Not reported	0	89	89
Blood group			
0	10	82	92
A	5	40	45
В	0	9	9
AB	1	3	4
Not reported	2	5	7
CMV serology			
Negative	7	39	46
Positive	10	45	55
Not reported	1	55	56

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

		Donors (n)	-
	2018	2002 - 2017	Total
Total	29	389	418
Age			
Mean (SD)	50.7 (10.1)	46.1 (13.0)	46.4 (12.9)
0-24	0	33	33
25-34	3	45	48
35-44	4	73	77
45+	22	237	259
Not reported	0	1	1
Sex			
Female	15	168	183
Male	14	218	232
BMI kg/m²			
Mean (SD)	27.7 (4.8)	28.8 (6.5)	28.7 (6.4)
Underweight (<18.5)	0	3	3
Normal weight (18.5-24)	13	123	136
Overweight (25-29)	8	130	138
Obese (30+)	8	132	140
Not reported	0	1	1
State of residence			
New South Wales	9	125	134
Victoria	8	120	128
Queensland	2	35	37
Western Australia	2	37	39
South Australia	3	49	52
Tasmania	2	13	15
Australian Capital Territory	3	2	5
Northern Territory	0	5	5
Not reported	0	3	3
Donor type		_	_
Brain dead (DBD)	2	249	251
Circulatory death (DCD)	16	140	156
Donor mode of death			
Cerebral hypoxia/ischaemia	8	50	58
Cerebral infarct	3	21	24
Intracranial haemorrhage	14	166	180
Non-neurological condition	1	33	34
Other neurological condition	0	12	12
Traumatic brain injury	2	35	37
Not reported	1	64	65
Days ventilated prior to donation	_	J .	
Mean (SD)	3.4 (1.9)	2.9 (2.3)	2.9 (2.3)

Alcohol consumption			
Never	8	35	43
Former	0	5	5
Current	16	208	224
Not reported	5	141	146
Smoking history			
Never	13	87	100
Former	2	19	21
Current	14	174	188
Not reported	0	109	109
Cultural and ethnic group			
Indigenous Australian or Torres Strait Islander	0	1	1
Maori or Pacific Islander	0	1	1
White	28	249	277
North East Asian (Chinese)	0	1	1
South East Asian	1	4	5
South and Central Asian (Indian)	0	1	1
Middle Eastern or North African	0	0	0
Other	0	3	3
Not reported	0	129	129
Blood group			
0	16	206	222
A	10	140	150
В	0	26	26
AB	1	11	12
Not reported	2	6	8
CMV serology			
Negative	13	149	162
Positive	15	125	140
Not reported	1	75	76

Donors who provided pancreata 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 2018

·	Donors (n)			
	Westmead	St Vincent's	Total	
Total	6	8	14	
Age				
Mean (SD)	45.2 (8.7)	56.8 (6.8)	51.8 (9.5)	
0-24	0	0	0	
25-34	1	0	1	
35-44	1	0	1	
45+	4	8	12	
Sex				
Female	3	5	8	
Male	3	3	6	
BMI kg/m ²				
Mean (SD)	32.0 (6.9)	26.7 (3.1)	29.0 (5.6)	
Underweight (<18.5)	0	0	0	
Normal weight (18.5-24)	2	3	5	
Overweight (25-29)	0	4	4	
Obese (30+)	4	1	5	
State of residence				
New South Wales	4	2	6	
Victoria	0	5	5	
Queensland	1	0	1	
Western Australia	0	0	0	
South Australia	0	1	1	
Tasmania	0	0	0	
Australian Capital Territory	1	0	1	
Northern Territory	0	0	0	
Not reported	0	0	0	
Donor type				
Brain dead (DBD)	6	8	14	
Circulatory death (DCD)	0	0	0	
Donor mode of death				
Cerebral hypoxia/ischaemia	0	2	2	
Cerebral infarct	2	1	3	
Intracranial haemorrhage	4	4	8	
Non-neurological condition	0	0	0	
Other neurological condition	0	0	0	
Traumatic brain injury	0	0	0	
Not reported	0	1	1	
Days ventilated prior to donation				
Mean (SD)	3.7 (1.8)	3.8 (2.1)	3.8 (1.9)	
Alcohol consumption				

Never	1	0	1
Former	0	0	0
Current	5	8	13
Smoking history			
Never	4	4	8
Former	0	0	0
Current	2	4	6
Cultural and ethnic group			
Indigenous Australian or Torres Strait Islander	0	0	0
Maori or Pacific Islander	0	0	0
White	5	8	13
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
Blood group			
0	4	6	10
A	2	2	4
В	0	0	0
AB	0	0	0
CMV serology			
Negative	3	2	5
Positive	3	5	8
Not reported	0	1	1

Islet transplant recipients

Figure 4.1 illustrates the number of islet cell transplants in Australia between 2002 and 2018. The transplants were performed in Westmead (68), St Vincent's (30), and Royal Adelaide (18) Hospitals. In 2018, 5 transplants were performed at Westmead, 7 at St Vincent's and 2 at the Royal Adelaide.

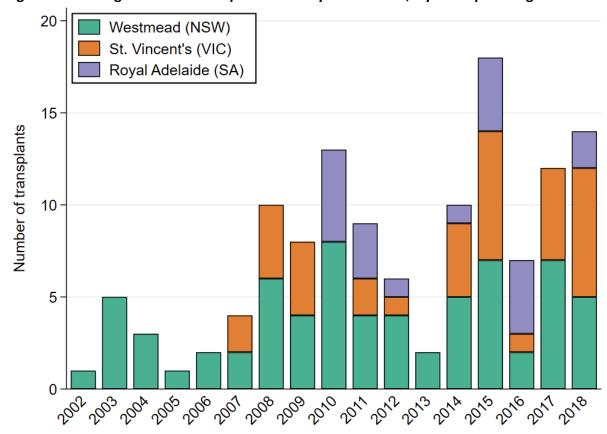


Figure 4.1: Allogenic islet transplant activity 2002-2018, by transplanting centre

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, 2002-2018, from allogenic islet transplants undertaken in Westmead Hospital (NSW)

Desirient blood every		Donor blood group				
Recipient blood group	0	Α	В	AB	Not reported	Total
0	0	0	0	0	19	19
A	0	0	0	0	39	39
В	0	0	0	0	4	4
AB	0	1	0	0	5	6
Total	0	1	0	0	67	68

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

Table 4.10: Cross tabulation of recipient and donor blood groups, 2002-2018, from allogenic islet transplants undertaken in St Vincent's hospital (VIC)

Desirient bland succes		Donor blood group						
Recipient blood group	0	Α	В	AB Not reported		Total		
0	9	0	0	0	1	10		
Α	3	9	0	0	0	12		
В	3	0	2	0	1	6		
AB	0	1	0	1	0	2		
Total	15	10	2	1	2	30		

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

Table 4.11: Cross tabulation of recipient and donor blood groups, 2002-2018, from allogenic islet transplants undertaken in Royal Adelaide Hospital (SA)

Desirient blood averus		Total					
Recipient blood group	0	Α	В	AB	Not reported	Total	
0	9	0	0	0	1	10	
A	2	4	0	0	2	8	
В	0	0	1	0	1	2	
AB	0	0	0	0	0	0	
Total	11	4	1	0	4	20	

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

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, 2002-2018

Recipient sex		Donor sex						
	Female	Male	Not reported	Total				
Female	19	21	42	82				
Male	3	3	30	36				
Total	22	24	72	118				

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, 2002-2018, for allogenic islet transplants undertaken in Australia

Paciniant blood group		Total				
Recipient blood group	0	Α	В	AB	Not reported	IOLAI
0	18	0	0	0	21	39
A	5	13	0	0	41	59
В	3	0	3	0	6	12
AB	0	2	0	1	5	8
Total	26	15	3	1	73	118

Recipients could receive more than one transplant and therefore may be duplicated in numbers

State of residence of recipients receiving an islet transplant in 2018, 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, 2018)

Recipient state of residence	1st	2nd	3rd	Total
New South Wales	1	3	0	4
Victoria	0	0	0	0
Queensland	1	0	0	1
Western Australia	0	0	0	0
South Australia	1	1	0	2
Tasmania	0	0	0	0
Australian Capital Territory	0	0	0	0
Northern Territory	0	0	0	0
Total	3	4	0	7

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 2018

Recipient state					Donor	state o	f reside	ence		
of residence	NSW	VIC	QLD	SA	WA	TAS	ACT	NT	Not reported	Total
NSW	0	0	0	0	0	0	0	0	4	4
VIC	0	0	0	0	0	0	0	0	1	1
QLD	0	0	0	0	0	0	0	0	0	0
SA	0	0	0	1	0	0	1	0	0	2
WA	0	0	0	0	0	0	0	0	0	0
TAS	0	0	0	0	0	0	0	0	0	0
ACT	0	0	0	0	0	0	0	0	0	0
NT	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	1	0	0	1	0	5	7

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 2002-2018

Recipient state	Donor state of residence									
of residence	NSW	VIC	QLD	WA	SA	TAS	ACT	NT	Not reported	Total
NSW	0	1	0	0	0	0	0	0	56	57
VIC	0	18	0	1	5	3	0	1	2	30
QLD	0	0	0	0	0	0	0	0	2	2
WA	0	0	0	0	0	0	0	0	8	8
SA	2	7	0	0	5	2	1	0	3	20
TAS	0	0	0	0	0	0	0	0	0	0
ACT	0	0	0	0	0	0	0	0	1	1
NT	0	0	0	0	0	0	0	0	0	0
Total	2	26	0	1	10	5	1	1	72	118

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)	
	2018	2002-2017	Total
Total	3	55	58
Age			
Mean (SD)	43.7 (15.9)	47.4 (11.4)	47.2 (11.5)
0-24	0	2	2
25-34	1	4	5
35-44	1	14	15
45+	1	35	36
Sex			
Female	1	38	39
Male	2	17	19
State of residence			
New South Wales	1	25	26
Victoria	0	15	15
Queensland	1	1	2
Western Australia	0	4	4
South Australia	1	9	10
Tasmania	0	0	0
Australian Capital Territory	0	1	1
Northern Territory	0	0	0
Blood group			
0	2	19	21
А	1	25	26
В	0	7	7
AB	0	4	4
Number of transplants per recipient			
1	1	14	15
2	2	24	26
3	0	17	17
Wait time from listing to first transplant			
0-1 years	2	14	16
1-2 years	1	2	3
2+ years	0	2	2
Not reported	0	37	37
Insulin independent post-transplant			
Yes	1	20	21
No	2	35	37

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 2002-2018 is presented in Figure 4.2. Data were available for 101 patients added to the waiting list before 31st December 2018, 58 of whom have received at least one transplant during this period. However, the date of waitlisting is known for only 59 patients, 21 of whom received at least one transplant as of 31st December 2018. The median time to first transplant has not yet been reached (25th percentile 0.99 years).

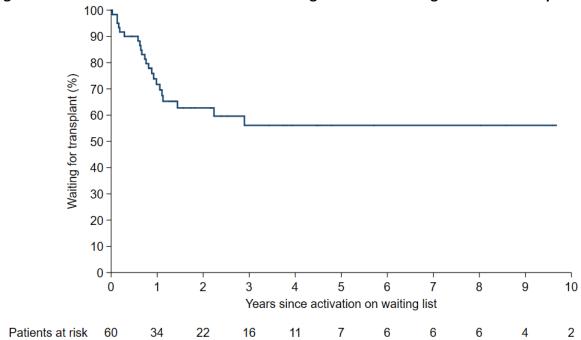


Figure 4.2: Time from activation on a waiting list to first allogenic islet transplant

The time from first to second islet transplant for 2002-2018 is presented in Figure 4.3. Recipients waited a median of 1.10 years from first transplant to receiving a second transplant (IQR 0.36-13.63 years).

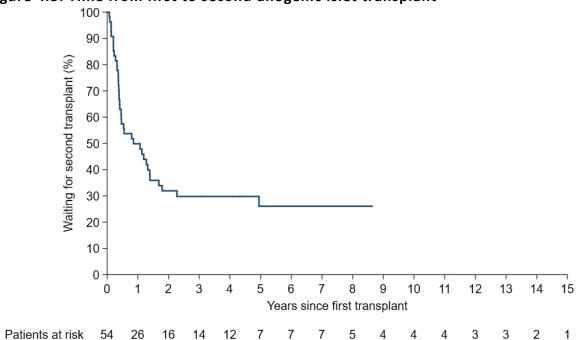


Figure 4.3: Time from first to second allogenic islet transplant

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 2002-2018 is presented in Figure 4.4. The median time from second transplant to third transplant has not yet been reached (25th percentile 0.84 years), likely due to many recipients not requiring a third transplant.

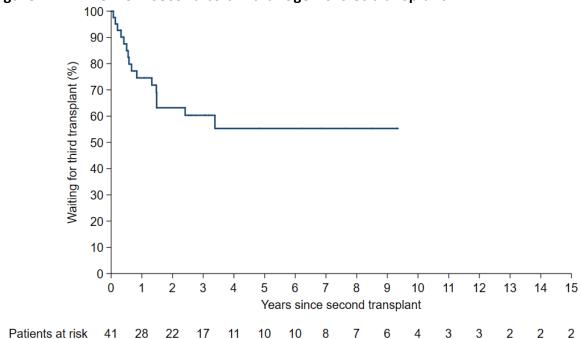


Figure 4.4: Time from second to third allogenic islet transplant

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.

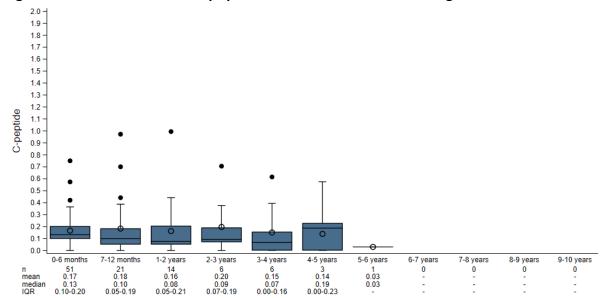


Figure 4.5: Distribution of c-peptide over time since first allogenic islet infusion

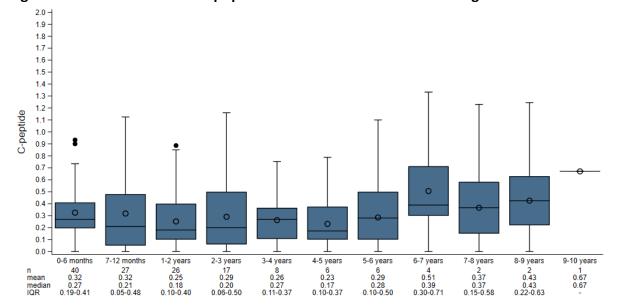
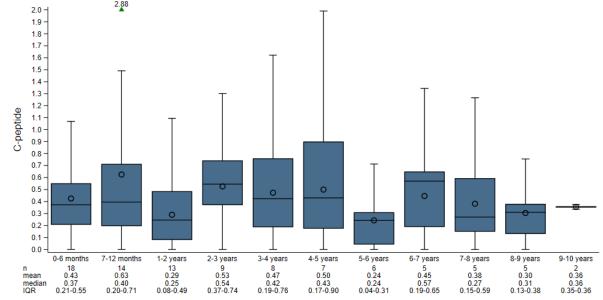


Figure 4.6: Distribution of c-peptide over time since second allogenic islet infusion





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.

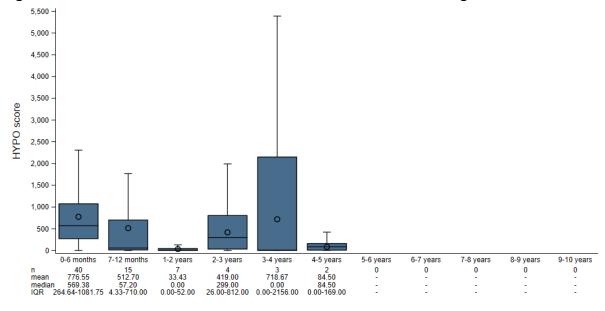


Figure 4.8: Distribution of HYPO score over time since first allogenic islet infusion

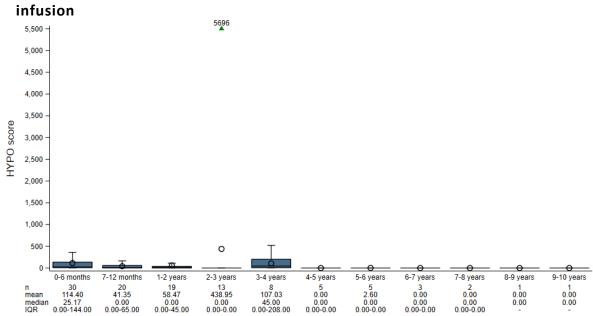
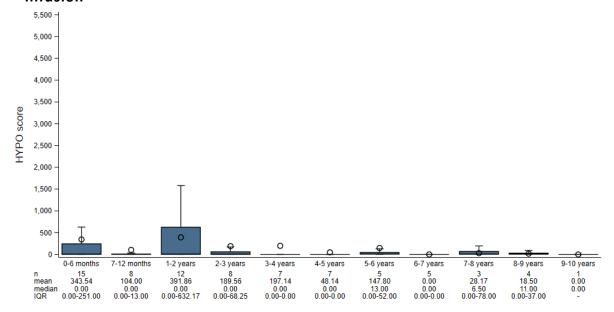


Figure 4.9: Distribution of HYPO score over time since second allogenic islet

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.

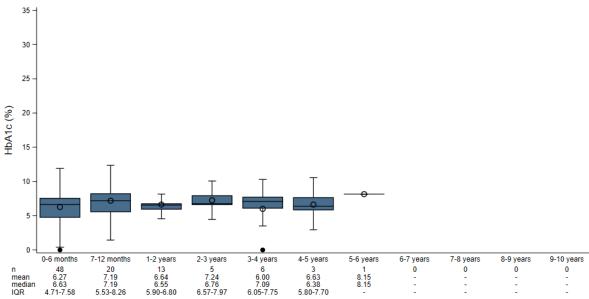
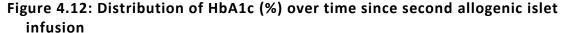
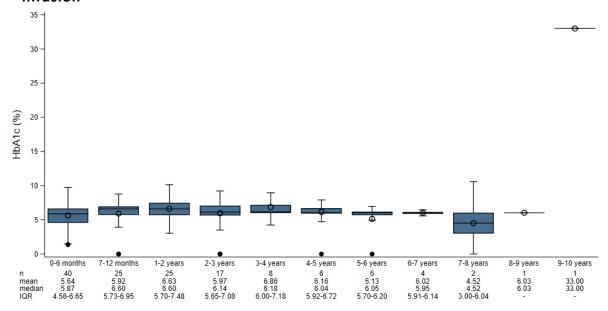


Figure 4.11: Distribution of HbA1c (%) over time since first allogenic islet infusion





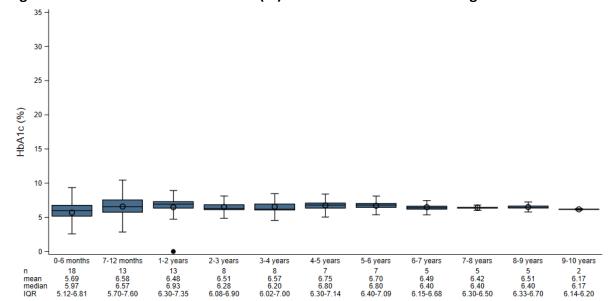


Figure 4.13: Distribution of HbA1c (%) over time since third allogenic islet infusion

Insulin independence is defined as a person being free from insulin use for at least 14 days. There are 20 patients who have achieved insulin independence; 2 patients after their first transplant, 11 patients after their second transplant, and 7 patients after their third transplant. The duration of insulin independence from the time insulin was first ceased for 2002-2018 is presented in Figure 4.14.

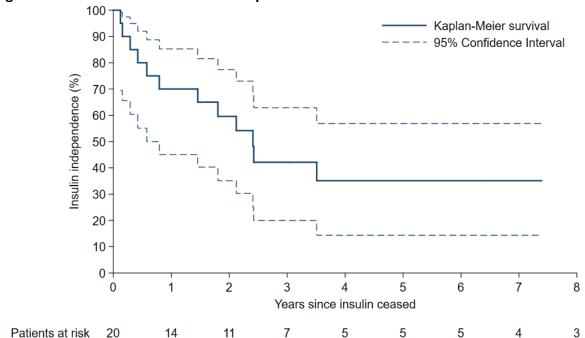


Figure 4.14: Duration of insulin independence from time first ceased

Chapter 5: Islet auto-transplants

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

Total Pancreatectomy and Autologous Islet Transplantation (auto-islet transplant, TP-IAT) 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 (Hereditary Pancreatitis, HP), diseases of the pancreas which cause them severe and chronic pain. The most common genetic causes of hereditary pancreatitis are genetic abnormalities in the PRSS-1 gene, SPINK-1 gene, and other genes in the trypsinogen pathway. 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. In cases where chronic pancreatitis is due to HP there is a significant risk of development of adenocarcinoma of the pancreas by middle age. In these cases, TP-IAT may also be regarded as preventing pancreatic adenocarcinoma. 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 2018 is presented in Table 5.1.

Table 5.1: Patients waiting for an auto-islet transplant at the end of 2018, by transplant centre

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

For auto-islet transplants occurring in Adelaide, the pancreatectomy 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	
2018	1	2	2	
2017	0	3	3	
2016	1	1	1	
2015	1	1	1	
2014	0	0	0	
2013	0	0	0	
2012	0	0	0	
2011	0	0	0	
2010	1	0	0	
Total	4	7	7	

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

Characteristic, mean (SD)	2018	2010-2017	Total
Patients (n)	3	8	11
Age	24.3 (18.1)	23.6 (13.9)	23.8 (14.2)
Patient weight	48.5 (26.2)	62.6 (16.4)	55.6 (21.0)
Pancreas weight	23.7 (-)	44.3 (24.8)	39.2 (22.7)
Islet equivalent (IEQ) total ('000)	137 (14.1)	230 (67.5)	183 (67.1)
Islet equivalent (IEQ) per kilogram ('000)	3.9 (3.0)	4.0 (2.0)	4.0 (2.3)

Appendices

ANZIPTR Annual Report 2018

An abridged version of the ANZIPTR annual report for 2018 pancreas chapters (chapters 1-3) was published in Transplantation Direct, and can be viewed here:

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6233667/

The ANZIPTR annual report for 2018 pancreas chapters should be cited as follows:

AC Webster et al., Transplantation Direct. 2018; 4(10): e390

An abridged version of the ANZIPTR annual report for 2018 islets chapters (chapters 4-5) was also published in Transplantation Direct, and can be viewed here:

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6415971/

The ANZIPTR annual report for 2018 islet chapters should be cited as follows:

AC Webster et al., Transplantation Direct. 2019; 5(2): e421

Other abstracts and publications

Data from ANZIPTR was used in the following abstracts that were presented at conferences in 2018:

Conference: Transplant Society of Australia and New Zealand (TSANZ) Annual Scientific

Meeting

Location: Melbourne, Australia **Date:** 29th April – 1st May 2018

Authors: Webster, A; Hedley, J; Kelly, P

Title: Post-Transplant Survival in Type 1 Diabetics in Australia and New Zealand

Conference: The Transplantation Society (TTS) Annual Scientific Meeting

Location: Madrid, Spain

Date: 30th June – 5th July 2018

Authors: Hedley, J; Kelly, P; Webster, A

Title: Post-Transplant Survival in Type 1 Diabetics in Australia and New Zealand

Conference: Australian and New Zealand Society of Nephrology (ANZSN) Annual Scientific

Meeting

Location: Sydney, Australia **Date:** 8th - 12th September 2018

Authors: Hedley, J; Kelly, P; Webster, A

Title: Kidney graft survival and patient survival in type 1 diabetics after kidney transplant

alone compared to simultaneous pancreas-kidney transplant