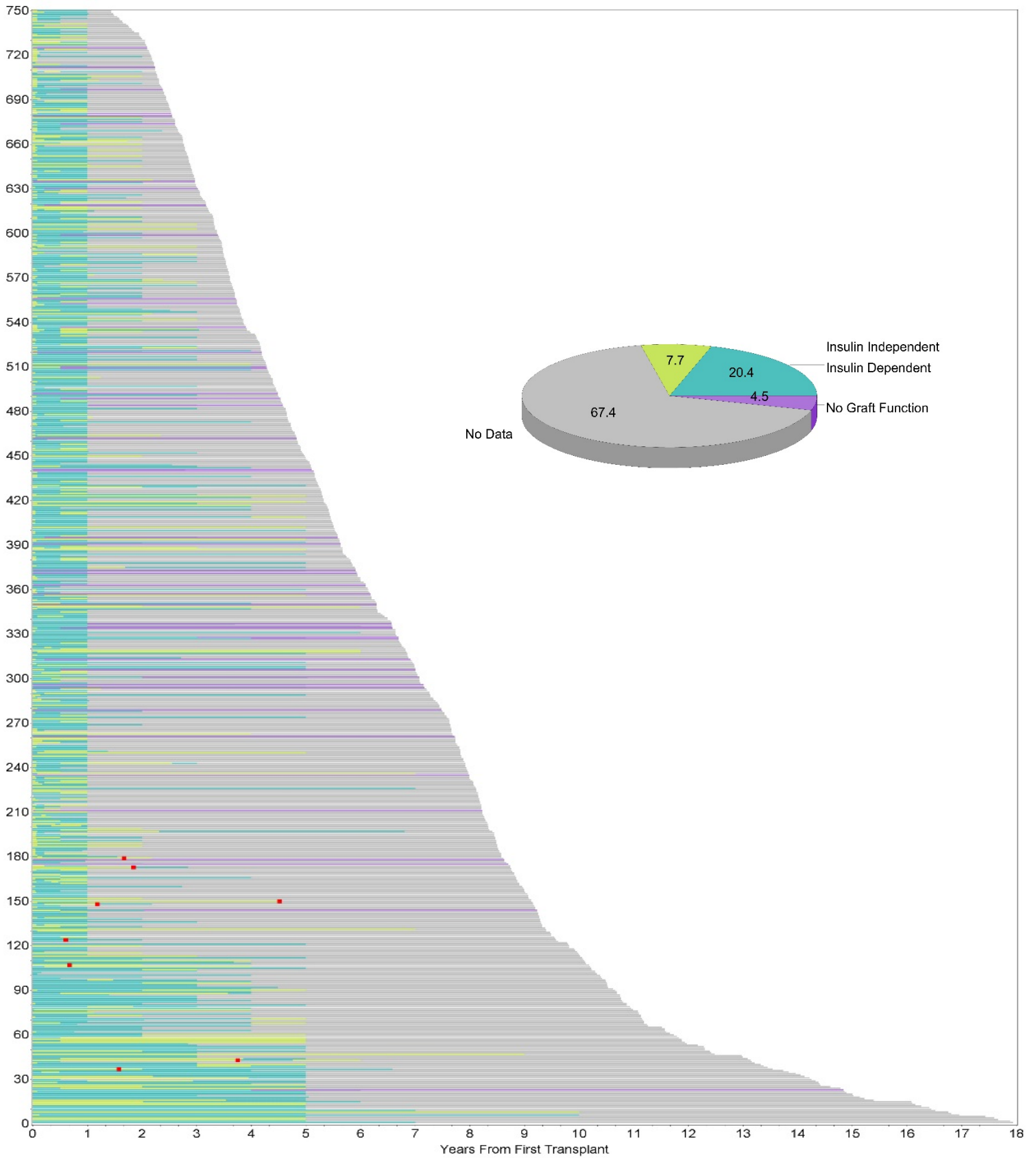**citr**

Collaborative Islet Transplant Registry

Inaugural Report on Autologous Islet Transplantation

Prepared by:
CITR Coordinating Center
The Emmes Corporation
Rockville, MD

Sponsored by:
National Institute of Diabetes and Digestive and Kidney Diseases
National Institutes of Health
US Department of Health and Human Services
Bethesda, MD

January 6, 2017

Collaborative Islet Transplant Registry 2016

Islet Autografts
Yellow: insulin independent; Green: insulin-using with graft function;
Black: no islet function (C-peptide<0.3 ng/ml); Gray: missing data; Red: re-infusions.
Pie charts show percent of all follow-up time.

COLLABORATIVE ISLET TRANSPLANT REGISTRY

COORDINATING CENTER

23 August 2018

M E M O R A N D U M

TO: CITR Collaborators, Islet Transplant Centers, Diabetes Research Community, and Interested Public

FROM: Thomas Eggerman, MD, PhD
Guillermo Arreaza-Rubin, MD
Program Directors, Division of Diabetes, Endocrinology and Metabolic Diseases
National Institute of Diabetes and Digestive and Kidney Diseases

              Melena Bellin, MD
CITR Autograft Working Group Chair and
CITR Executive Committee

SUBJECT: CITR Inaugural Report on Autologous Islet Transplantation

Funded by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) with supplemental funding from the Juvenile Diabetes Research Foundation (JDRF) for 2006-2015, the Collaborative Islet Transplant Registry (CITR) serves the mission to expedite progress and promote safety in islet/beta cell transplantation through the collection, analysis, and communication of comprehensive and current data on human-to-human islet/beta cell transplants performed in North America, and Juvenile Diabetes Research Institute-sponsored European and Australian sites.

We are pleased to present the CITR **Inaugural Report on Autologous Islet Transplantation (infusions as of Sep 2015, follow-up as of Jan 2017)** including data from the majority of the auto-islet transplant programs active in 1999-2016.

The report has been prepared by staff of The Emmes Corporation under the leadership of the CITR Publications and Presentations Committee chaired by Dr. Michael Rickels, and CITR Coordinating Center Principal Investigator, Ms. Franca Benedicty Barton.

We thank everyone who has contributed data and collaborated in the development of the CITR Registry and the production of this Report, including the islet transplant programs and especially the islet recipients who voluntarily consent to the submission of their information. We look forward to their continued participation, along with that of all centers and organizations active in islet transplantation.

Chapter 1
Autologous Islet Transplant Activity

Table of Contents

Introduction

This report is based on autologous islet transplant (Auto-Itx) recipients registered in the Collaborative Islet Transplant Registry (CITR), infused from 1999 through September 2015, with follow-up data through December 2016.

Of 23 North American sites performing Auto-ITx during this period, 11 reported data to CITR, along with 4 European and Australian islet transplant centers. These sites registered 819 auto-islet transplant recipients. Of these, 754 recipients were in North America, 63 in Europe, and 2 in Australia. Ninety-six (96) were aged less than 18, and 723 were 18 or older at the time of their transplant. Eight (8) of the total recipients received a second auto-islet transplant. Exhibits 1-1A and 1-1B summarize the total allograft recipients and infusions included in this report. The increase in islet autotransplant over time is likely reflective of increasing awareness and acceptance of total pancreatectomy with Auto-Itx as a therapy for refractory pancreatitis.

Exhibit 1-2 shows the cumulative enrollment by date of transplant of all the Auto-ITx in CITR, by less than 18 years old and 18 and up. Exhibit 1-3 shows the number of clinical sites by year performing Auto-ITx. As with Allo-Itx, after the initial rise in annual transplants performed from 1999 through 2007, with subsequent leveling off thereafter. The light gray bars show the sites already members of CITR or identified via an online survey conducted by CITR, while the dark gray bars show the transplants registered in CITR. A few additional cases of Auto-Itx may be performed at sites not affiliated with an islet processing center, but those would be few.

Exhibit 1-4A shows the number of new Auto-Itx recipients by year from 1999. Exhibit 1-4B shows the number of new Auto-Itx annually reported to CITR by the European and Australian sites. Total pancreatectomy with Auto-Itx has not been endorsed as a procedure for chronic pancreatitis as largely abroad as in the US, with certain exceptions by country. The United Kingdom specifically has utilized Auto-Itx but has been more limited in scope in recent years due to limited funding for the procedure from the National Health System.

Exhibit 1-5 shows the second infusion by year. These are very few, performed only in cases where a partial pancreatectomy with Auto-Itx is first performed, and then due to treatment failure (persistent pancreatic disease), a completion pancreatectomy with Auto-Itx is then performed.

Exhibit 1-6 breaks down the new recipients by year adult vs. pediatric. Auto-Itx has been increasingly utilized in the care of children with chronic pancreatitis over the past decade, although the majority of cases are still performed in adult recipients

**Exhibit 1-1A
Auto-Islet Recipients**

CITR-Consented AUTO Recipients	North America	Europe	Australia	Total Recipients
N	754	63	2	819

**Exhibit 1-1B
Auto-Islet Infusions**

| AUTO Infusions | Pediatric | | Adult | | Total Infusions |
	North America	Europe/ Australia	North America	Europe/ Australia	
N	96	2	665	64	827

**Exhibit 1-2
Cumulative Auto-Islet Recipient Enrollment (by date of transplant)**
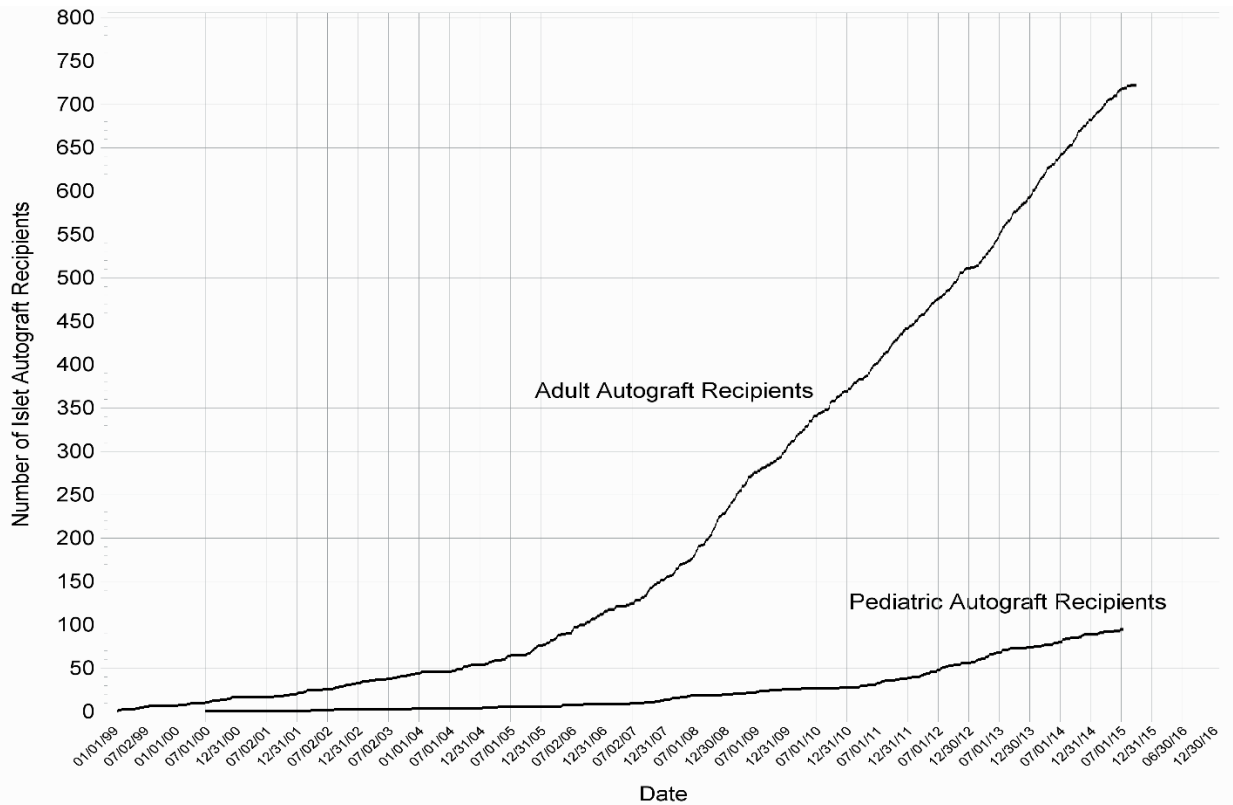
Exhibit 1-3
Clinical sites performing islet autograft transplantation, by year – North America

CITR Data 06Jan2017
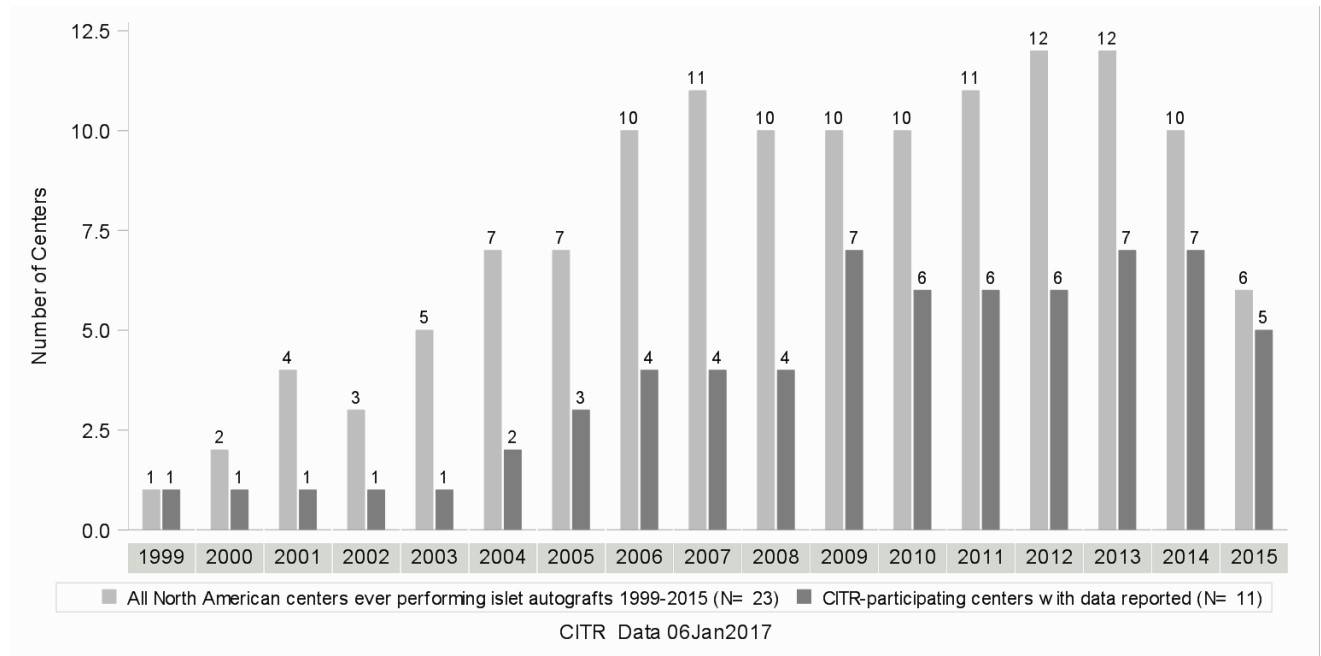
Exhibit 1-4A
**New islet autograft transplant enrollment, by year of first transplant –
North America**

CITR Data 06Jan2017
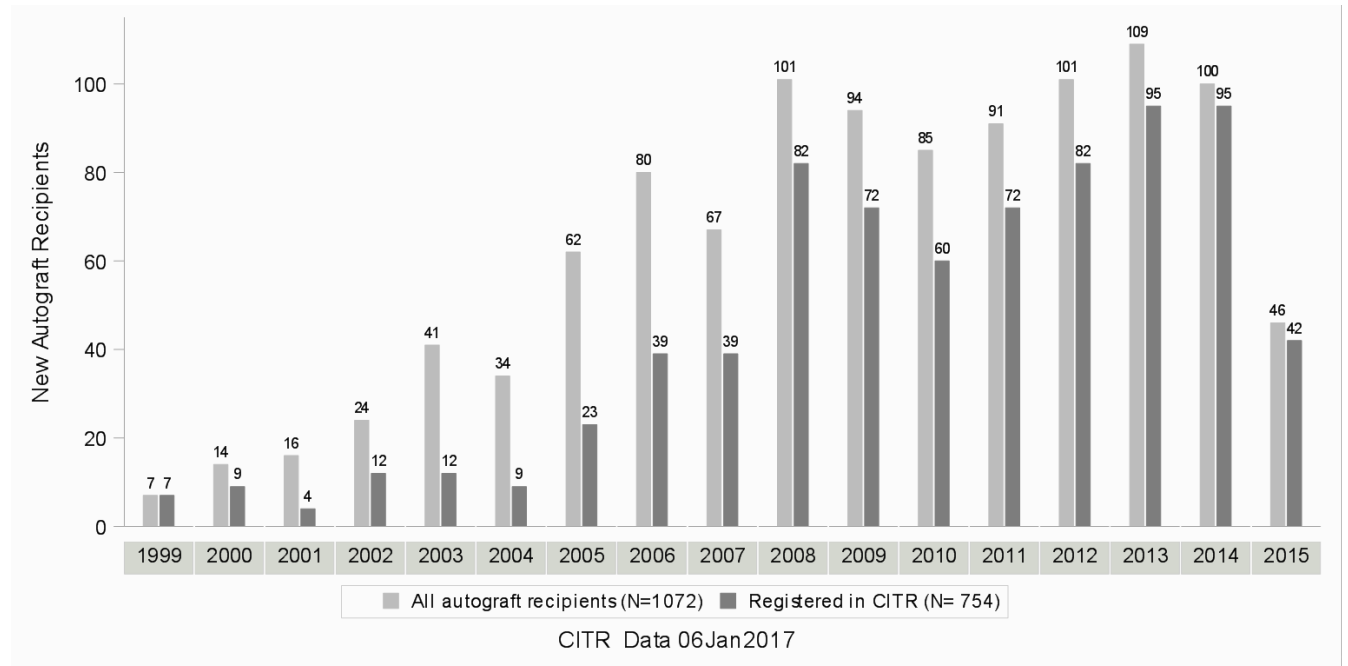
Exhibit 1-4B
New islet autograft transplant enrollment, by year of first transplant –
Europe and Australia
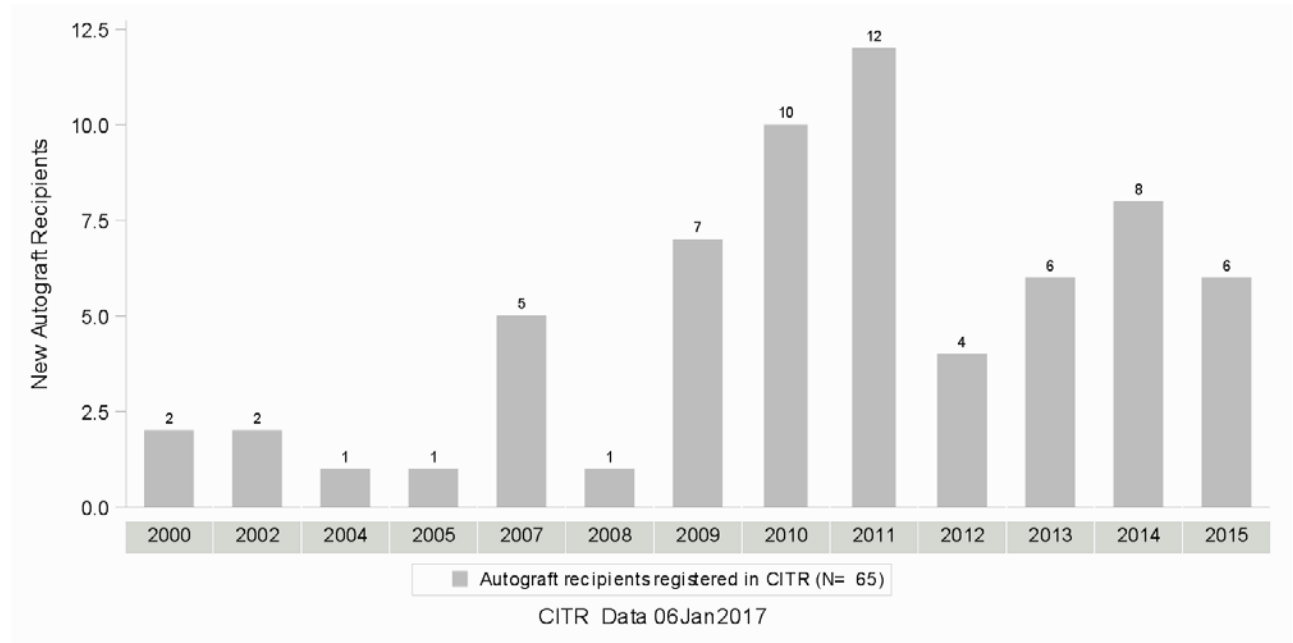
Exhibit 1-5
First and second autograft transplants, by year of transplant

CITR Data 06Jan2017
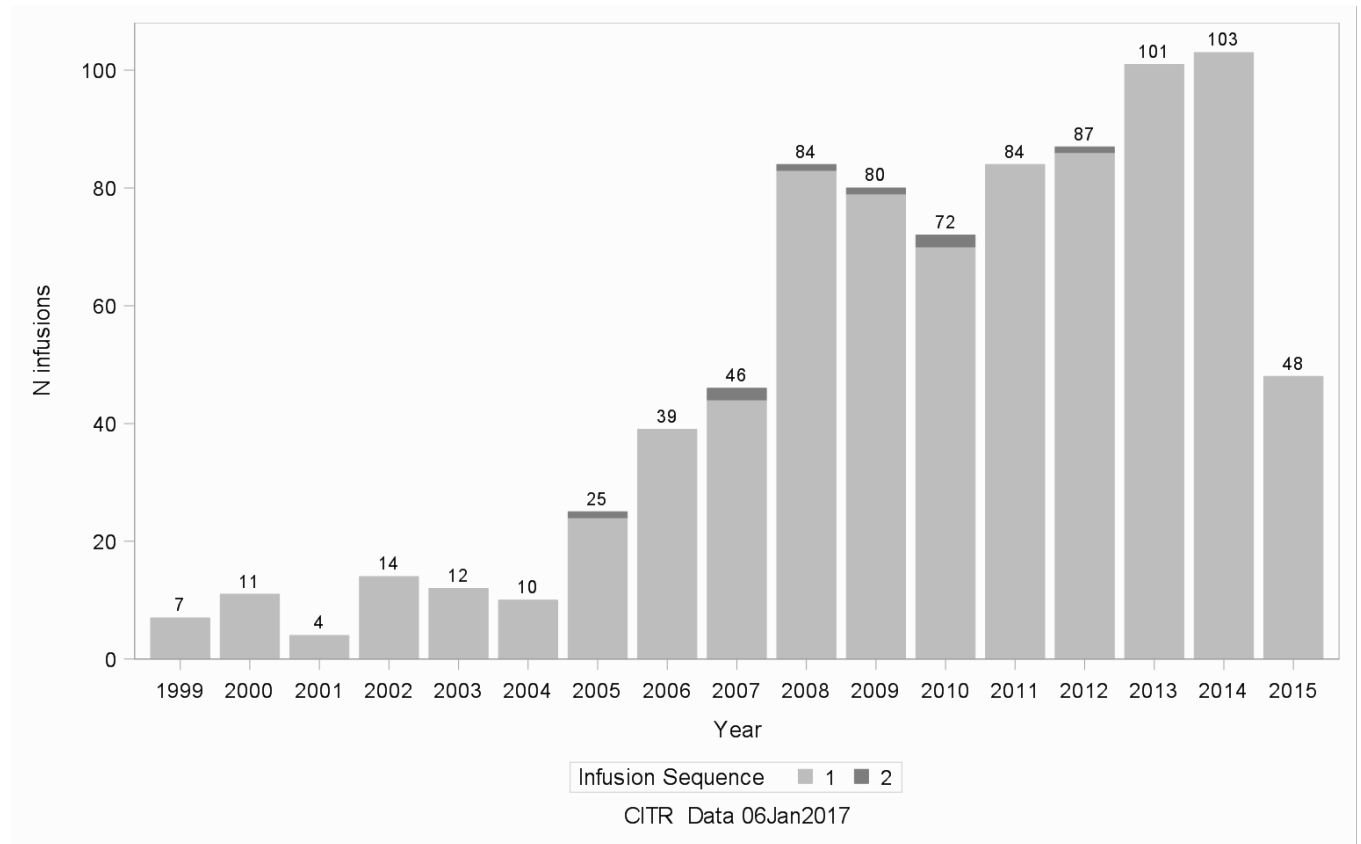
Exhibit 1-6
Adult and pediatric autograft transplants, by year of transplant

CITR Data 06Jan2017
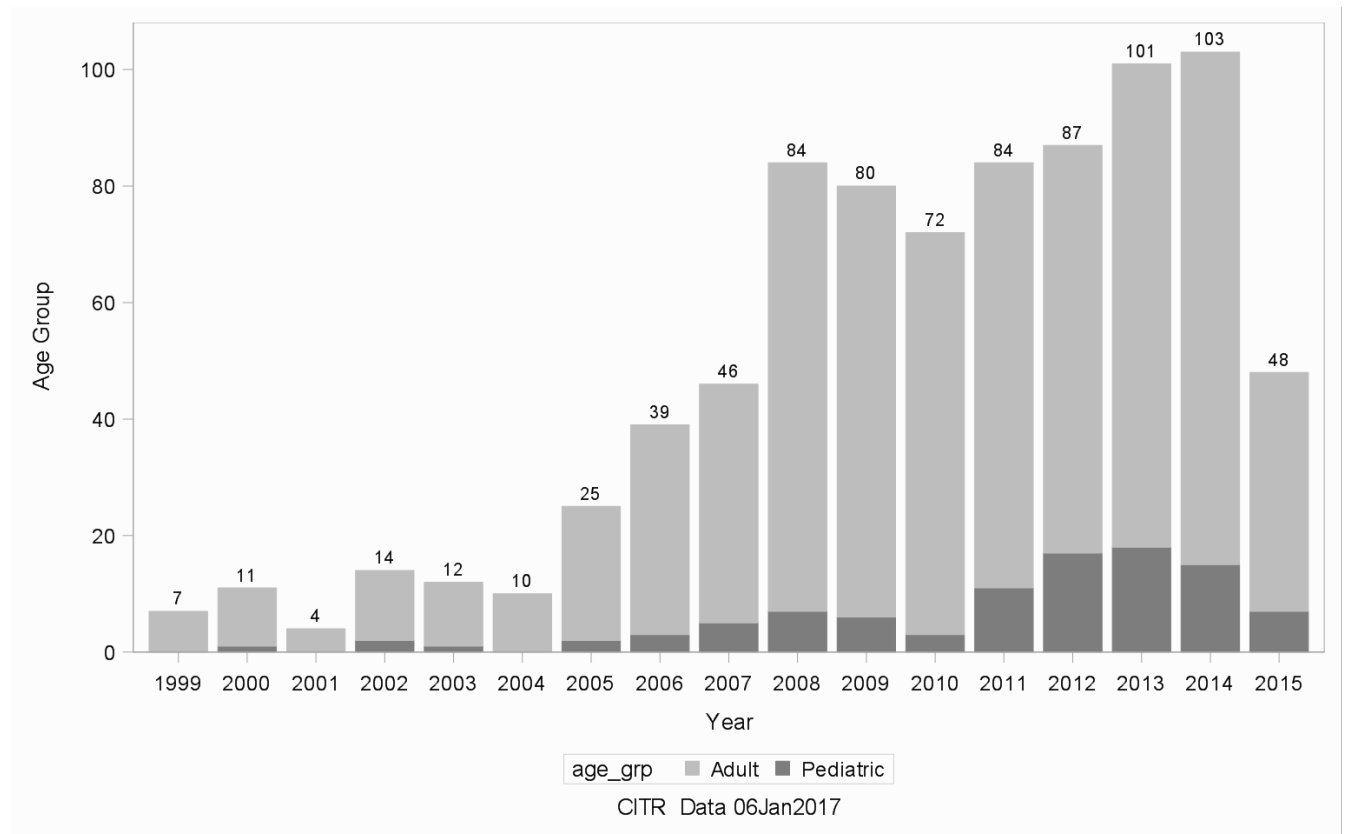
Chapter 2
Autologous Islet Recipient Characteristics

Table of Contents

Introduction

This chapter details the available demographic and medical history information on islet autograft recipients registered in CITR.

Many of the data elements in the islet autograft segment of the CITR registry data are not available particularly from the earlier eras (1999-2010).   What results are available are presented in this Chapter.   Data missing is shown for each exhibit.   More than 50% of the data is missing except for gender, age and era. Less than 25% missing data is highlighted in green text.   Data missing at 25-50% levels are highlighted in yellow.

The gender distribution shows a substantial majority of females receiving auto-islet transplantation across all age groups, and across all eras (Exhibit 2-1).

The vast majority of recipients identify as Caucasian or white (Exhibit 2-1) across all age groups and eras.

Mean blood glucose was well in control, although it rose with increasing age (Exhibit 2-2) . Basal C-peptide was also well above 0.3 ng/mL, with higher levels with increasing age. This would be expected since Auto-Itx is only performed in recipients with functioning beta cells to isolate and infuse.   HbA1c, though statistically significantly different across the age groups, ranged within normal levels.   As a mixture of indications for pancreatectomy and auto-islet transplantation, the CITR Auto-Itx group shows varying levels of insulin requirement prior to infusion: none of the children <12 years old (yo) required any insulin, 4% of the 12-18 yo's had required insulin, 2% of the the 18-<35 yo's required insulin, and 5% ≥35 yo's required insulin (Exhibit 2-2).

Differences in FBG, basal C-peptide and HbA1c over the eras of the Registry may reflect recent acceptance of performing Auto-Itx in diabetic patients with chronic pancreatitis when C-peptide levels are high. In early eras, diabetic patients were largely not considered candidates for Auto-Itx and total pancreatectomy alone was instead performed.

Both diagnostic and treatment ERCP as well as stent placement and nerve blockage increased with increasing age, while drainage and enzyme replacement were equally prevalent across age groups. Prior surgery was performed much less frequently among those <18 yo's, while Puestow was more prevalent among the <18 yo's.   (Exhibit 2-3

Total or completion pancreatectomy was done in 97% of the <35 yo's, and 87% of the ≥35 yo's. Across the eras, total pancreatectomy increased notably over the recent eras, likely reflecting only the varying age distribution in the recent eras.   (Exhibit 2-4)

Pancreatitis as the reason for the pancreatectomy declined from 100% in young children to 84% in ≥35 yo's (also reflected across the eras), while very few were done for treating cancer (Exhibit 2-4).

Pancreatitis duration did not differ remarkably across the age groups or by era (Exhibit 2-4). Familial pancreatitis was highly prevalent among the <18 yo's, sharply declining with increasing age.   Conversely, idiopathic etiology rose notably with increasing age, as did pancreas divisum and sphincter of Oddi dysfunction.   The differences in pancreatitis etiology across the eras are not clearly interpretable.

Any nominal differences in the laboratory values by age or era are based on too small a sample for any meaningful interpretation (Exhibit 2-5).

Exhibit 2-1
Recipient Demographics

		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Gender	Female	22	64.7	33	53.2	153	70.8	352	69.4	
	Male	12	35.3	29	46.8	63	29.2	155	30.6	

Data Completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Gender	Available	34	100.0	62	100.0	216	100.0	507	100.0	

		Era									
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
		N	%	N	%	N	%	N	%	N	%	p
Gender	Female	21	58.3	60	70.6	206	74.6	241	64.4	32	66.7	*
	Male	15	41.7	25	29.4	70	25.4	133	35.6	16	33.3	

Data completeness		Era									
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
		N	%	N	%	N	%	N	%	N	%
Gender	Available	36	100.0	85	100.0	276	100.0	374	100.0	48	100.0

*=p<.05; **=p<.01; ***=p<.001
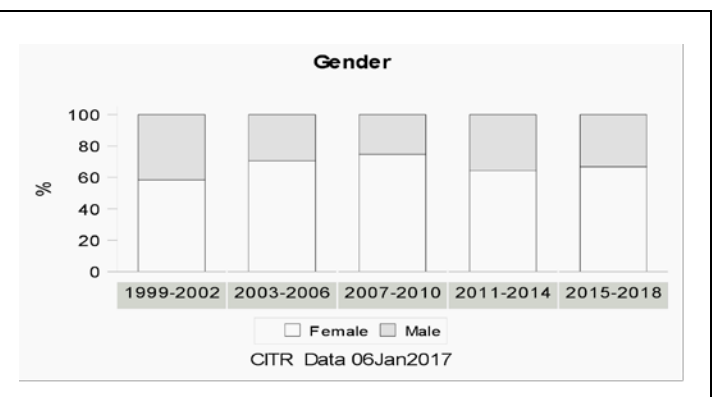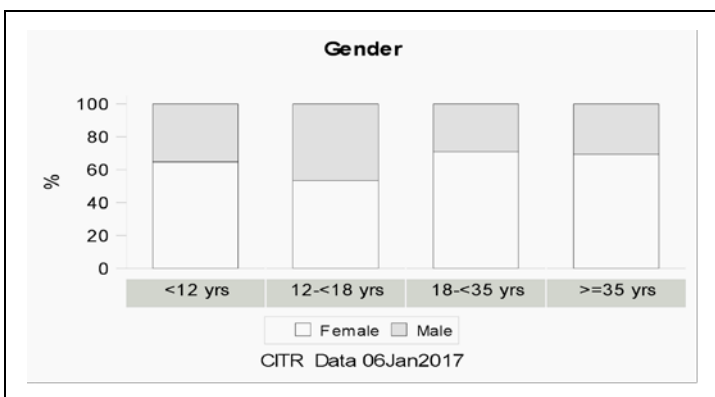
**Exhibit 2-1 (continued)
Recipient Demographics**

		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		Age Group								
		N	%	N	%	N	%	N	%	p
Race	**American Indian**		0.0		0.0	1	1.1	1	0.4	
	Asian		0.0		0.0		0.0	2	0.7	
	Black		0.0		0.0	3	3.3	17	6.2	
	Multiple	1	25.0		0.0		0.0		0.0	
	Other		0.0	1	11.1		0.0	2	0.7	
	White	3	75.0	8	88.9	87	95.6	251	91.9	

Data Completeness		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		Age Group								
		N	%	N	%	N	%	N	%	
Race	**Available**	4	11.8	9	14.5	91	42.1	273	53.8	
	Missing	30	88.2	53	85.5	125	57.9	234	46.2	

		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		
		Era										
		N	%	N	%	N	%	N	%	N	%	p
Race	**American Indian**		0.0		0.0		0.0	2	1.2		0.0	
	Asian	1	2.9		0.0	1	1.0		0.0		0.0	
	Black		0.0	2	4.3	8	8.0	9	5.3	1	3.8	
	Multiple		0.0		0.0		0.0	1	0.6		0.0	
	Other		0.0		0.0	1	1.0	1	0.6	1	3.8	
	White	33	97.1	44	95.7	90	90.0	158	92.4	24	92.3	

Data completeness		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		
		Era										
		N	%	N	%	N	%	N	%	N	%	
Race	**Available**	34	94.4	46	54.1	100	36.2	171	45.7	26	54.2	
	Missing	2	5.6	39	45.9	176	63.8	203	54.3	22	45.8	

*=p<.05; **=p<.01; ***=p<.001
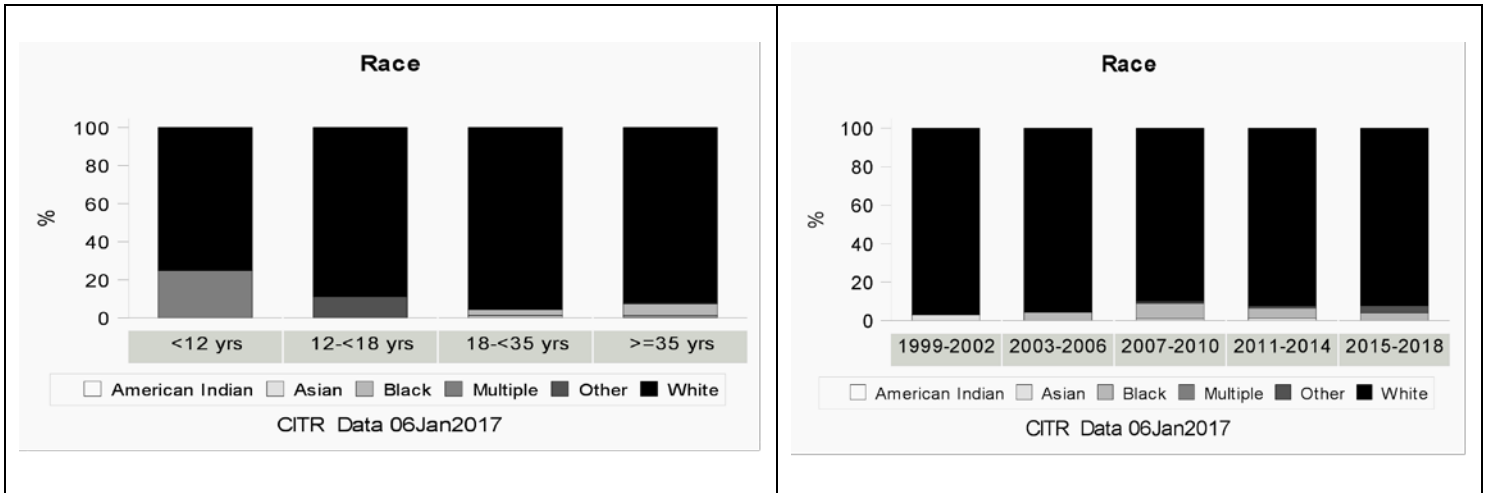
Exhibit 2-1 (continued)
Recipient Demographics

CITR Data 06Jan2017

Exhibit 2-1 (continued)
Recipient Demographics

		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Ethnicity	Hispanic		0.0		0.0	4	4.5	4	1.5	
	Not Hispanic	4	100.0	7	100.0	84	95.5	260	98.5	

		Age Group								
Data Completeness		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Ethnicity	Available	4	11.8	7	11.3	88	40.7	264	52.1	
	Missing	30	88.2	55	88.7	128	59.3	243	47.9	

		Era								
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
		N	%	N	%	N	%	N	%	N	%	p
Ethnicity	Hispanic		0.0		0.0	1	1.0	6	3.5	1	3.8	
	Not Hispanic	24	100.0	42	100.0	98	99.0	166	96.5	25	96.2	

		Era								
Data completeness		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
		N	%	N	%	N	%	N	%	N	%	
Ethnicity	Available	24	66.7	42	49.4	99	35.9	172	46.0	26	54.2	
	Missing	12	33.3	43	50.6	177	64.1	202	54.0	22	45.8	

*=p<.05; **=p<.01; ***=p<.001
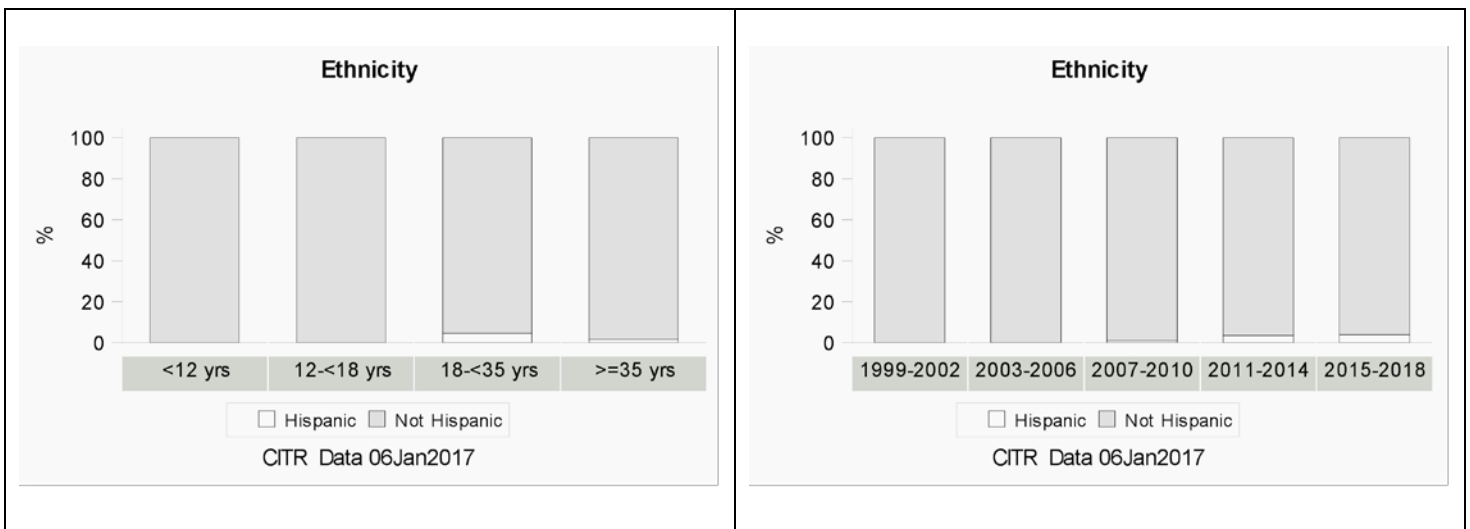
Exhibit 2-2
Recipient Characteristics at First Infusion

	Age Group												
	<12 yrs			12-<18 yrs			18-<35 yrs			>=35 yrs			
	N	Mean	SE	N	Mean	SE	N	Mean	SE	N	Mean	SE	p
Age at transplant	34	8.8	0.4	62	15.4	0.2	216	27.7	0.3	507	48.3	0.4	***
Weight (kg)	3	39.1	5.2	5	50.2	7.7	67	73.9	2.3	212	71.6	1.1	***
Body Mass Index (kg/m^2)	2	19.3	0.7	3	22.5	2.2	66	26.1	0.8	195	25.4	0.4	
Daily insulin requirement prior to infusion (units)	32	0.0	0.0	56	0.7	0.6	177	0.5	0.3	391	1.3	0.4	
Avg daily insulin / kg recipient body weight	3	0.0	0.0	5	0.0	0.0	49	0.0	0.0	156	0.0	0.0	
Fasting plasma glucose (mg/dL)	25	86.5	1.7	34	87.4	1.6	102	93.9	2.2	235	98.3	1.5	**
Basal C-Peptide (ng/mL)	29	1.4	0.2	47	1.9	0.1	167	2.3	0.1	379	2.1	0.1	*
HbA1c (%)	31	5.2	0.1	49	5.3	0.1	164	5.2	0.0	370	5.6	0.0	***

	Era															
	1999-2002			2003-2006			2007-2010			2011-2014			2015-2018			
	N	Mean	SE	N	Mean	SE	N	Mean	SE	N	Mean	SE	N	Mean	SE	p
Age at transplant	36	39.9	2.0	85	38.5	1.3	276	40.2	0.8	374	37.7	0.9	48	37.6	2.1	
Weight (kg)	4	61.9	8.7	11	67.4	3.6	82	66.9	1.7	168	72.4	1.3	22	84.8	5.5	***
Body Mass Index (kg/m^2)	4	21.6	1.9	9	25.1	1.8	71	24.1	0.7	161	25.5	0.4	21	30.8	1.5	***
Daily insulin requirement prior to infusion (units)	10	0.0	0.0	65	0.2	0.2	217	1.3	0.5	343	0.9	0.4	21	1.5	1.5	
Avg daily insulin / kg recipient body weight	4	0.0	0.0	2	0.0	0.0	41	0.0	0.0	146	0.0	0.0	20	0.0	0.0	
Fasting plasma glucose (mg/dL)	0	-	-	13	92.7	1.8	52	96.1	3.0	314	94.7	1.3	17	109.9	3.9	*
Basal C-Peptide (ng/mL)	4	1.4	0.3	17	2.6	0.4	231	2.2	0.1	350	2.0	0.1	20	2.9	0.4	**
HbA1c (%)	1	5.0	-	26	5.3	0.1	226	5.4	0.0	340	5.5	0.0	21	5.8	0.2	*

*=p<.05; **=p<.01; ***=p<.001

Exhibit 2-2 (continued)
Recipient Characteristics at First Infusion
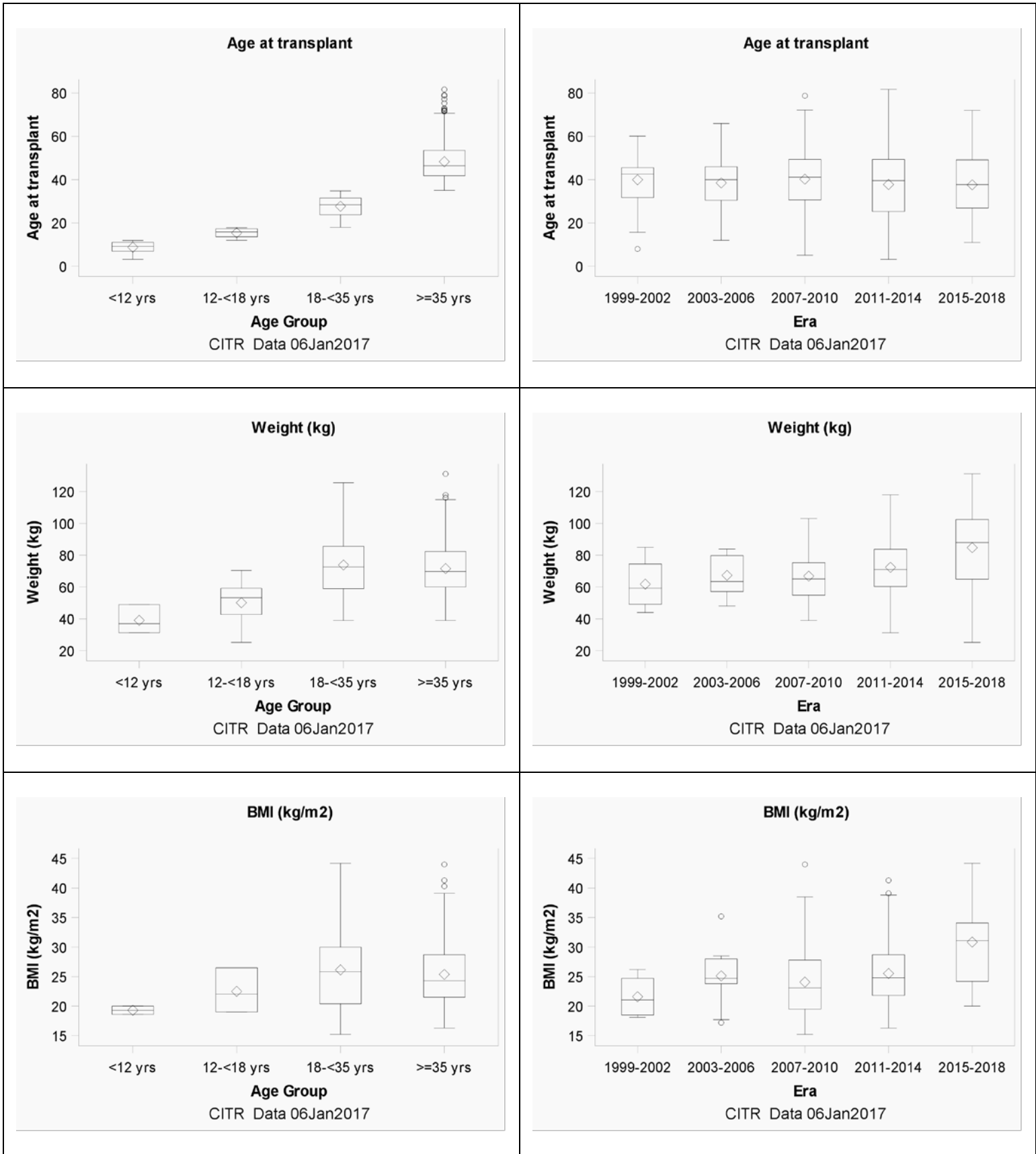
Exhibit 2-2 (continued)
Recipient Characteristics at First Infusion

Exhibit 2-2 (continued)
Recipient Characteristics at First Infusion

Basal C-Peptide (ng/mL) by Age Group — CITR Data 06Jan2017

Basal C-Peptide (ng/mL) by Era — CITR Data 06Jan2017

HbA1c (%) by Age Group — CITR Data 06Jan2017

HbA1c (%) by Era — CITR Data 06Jan2017
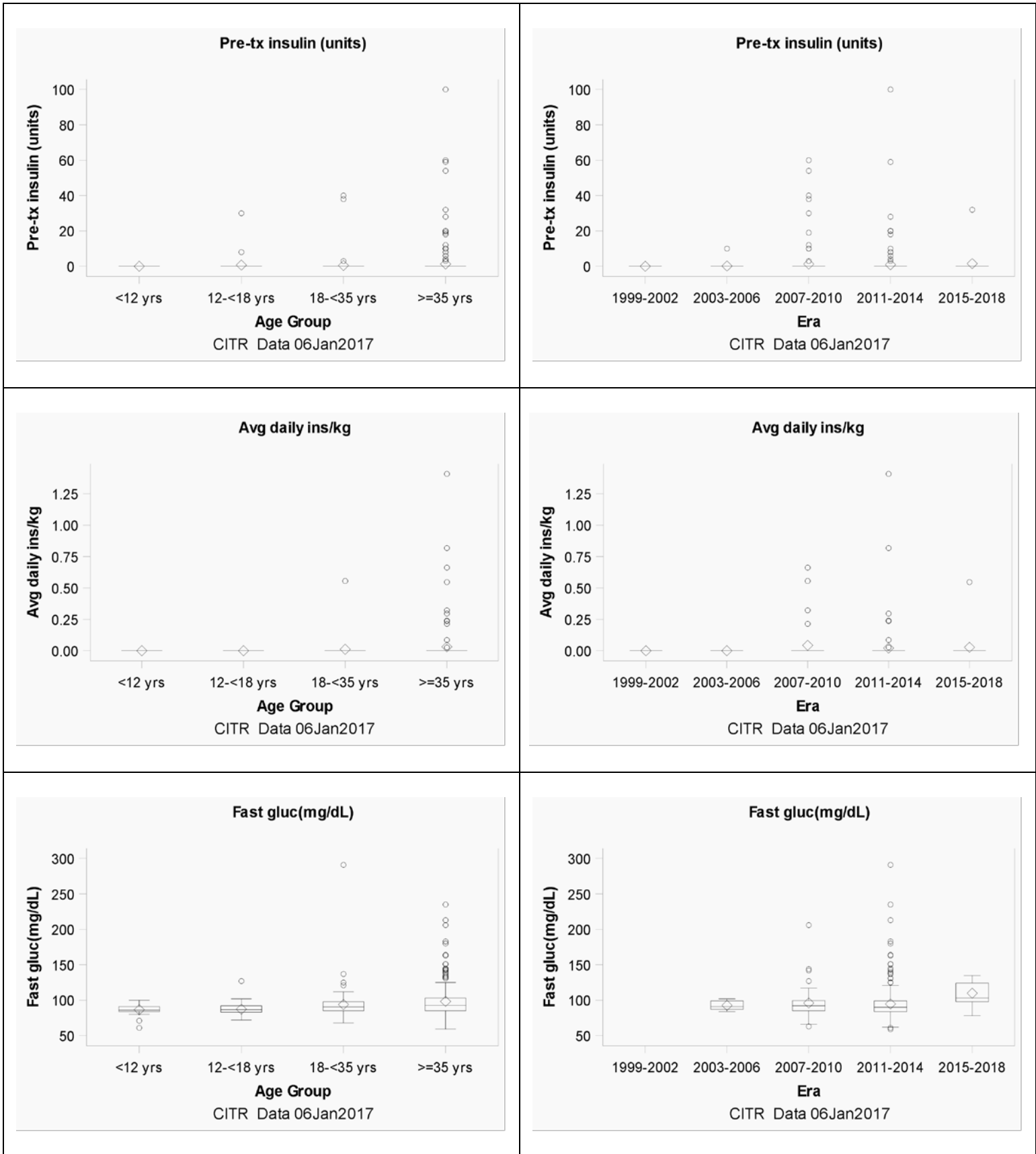
Exhibit 2-2B
Recipient Insulin Use at First Infusion

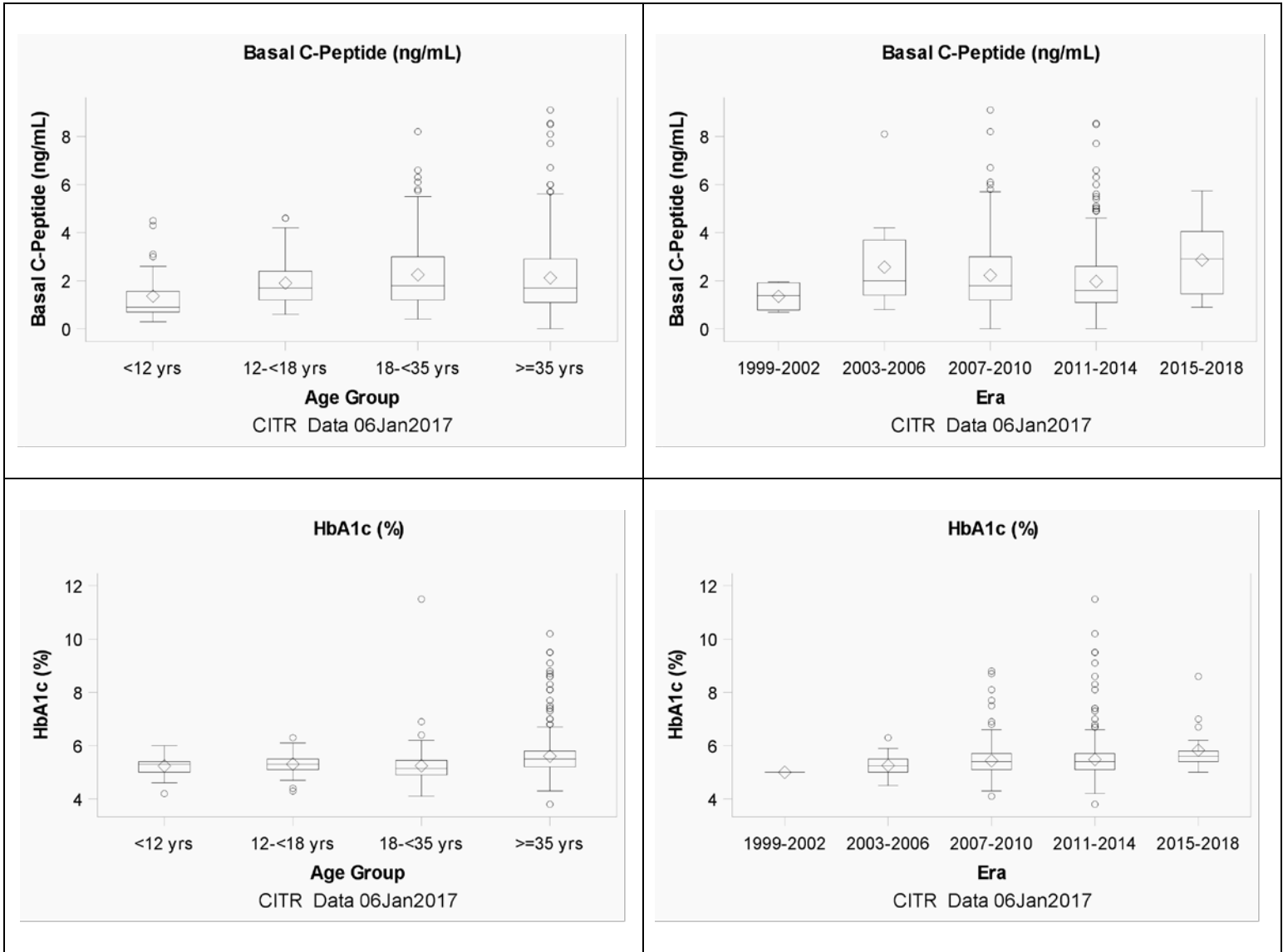|	Age group							
	<12 yrs		**12-<18 yrs**		**18-<35 yrs**		**>=35 yrs**	
	N	**%**	**N**	**%**	**N**	**%**	**N**	**%**
Baseline Daily Insulin Use (Units)								
Not on insulin	32	100.0	54	96.4	174	98.3	371	94.9
On insulin	-	-	2	3.6	3	1.7	20	5.1

Available data	Age group							
	<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs	
	N	%	N	%	N	%	N	%
Baseline Daily Insulin Use (Units)								
.	2	5.9	6	9.7	39	18.1	116	22.9
Not on insulin	32	94.1	54	87.1	174	80.6	371	73.2
On insulin	-	-	2	3.2	3	1.4	20	3.9

	Era									
	1999-2002		**2003-2006**		**2007-2010**		**2011-2014**		**2015-2018**	
	N	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
Baseline Daily Insulin Use (Units)										
Not on insulin	10	100.0	64	98.5	207	95.4	330	96.2	20	95.2
On insulin	-	-	1	1.5	10	4.6	13	3.8	1	4.8

Available data	Era									
	1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
	N	%	N	%	N	%	N	%	N	%
Baseline Daily Insulin Use (Units)										
.	26	72.2	20	23.5	59	21.4	31	8.3	27	56.3
Not on insulin	10	27.8	64	75.3	207	75.0	330	88.2	20	41.7
On insulin	-	-	1	1.2	10	3.6	13	3.5	1	2.1

Exhibit 2-3
Recipient Characteristics and Medical History

		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Hypoglycemia status	Aware		0.0		0.0		0.0	5	2.1	
	No Occurrence	13	100.0	20	100.0	82	97.6	229	96.2	
	Unaware		0.0		0.0	2	2.4	4	1.7	

Data Completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Hypoglycemia status	Available	13	38.2	20	32.3	84	38.9	238	46.9	
	Missing	21	61.8	42	67.7	132	61.1	269	53.1	

		Era										
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		
		N	%	N	%	N	%	N	%	N	%	p
Hypoglycemia status	Aware		0.0		0.0	2	2.5	3	1.3		0.0	
	No Occurrence	4	100.0	12	100.0	79	97.5	228	96.2	21	100.0	***
	Unaware		0.0		0.0		0.0	6	2.5		0.0	

Data completeness		Era									
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
		N	%	N	%	N	%	N	%	N	%
Hypoglycemia status	Available	4	11.1	12	14.1	81	29.3	237	63.4	21	43.8
	Missing	32	88.9	73	85.9	195	70.7	137	36.6	27	56.3

		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Severe Hypoglycemic Events	ASHE	32	100.0	56	100.0	198	100.0	453	99.6	
	SHE		0.0		0.0		0.0	2	0.4	

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Severe Hypoglycemic Events	Missing	2	5.9	6	9.7	18	8.3	52	10.3	
	Available	32	94.1	56	90.3	198	91.7	455	89.7	

Exhibit 2-3 (continued)
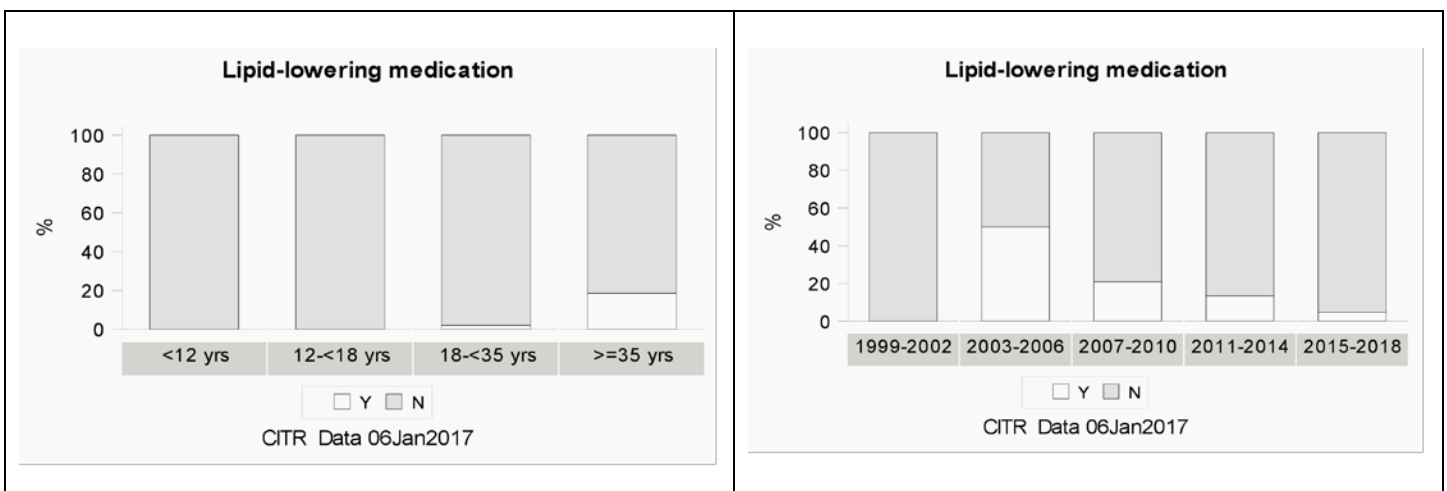**Recipient Diabetes Characteristics and Medical History**

		Era									
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
		N	%	N	%	N	%	N	%	N	%	p
Severe Hypoglycemic Events	ASHE	34	100.0	82	100.0	258	99.6	344	99.7	21	100.0	
	SHE		0.0		0.0	1	0.4	1	0.3		0.0	

Data completeness		Era									
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
		N	%	N	%	N	%	N	%	N	%
Severe Hypoglycemic Events	Missing	2	5.6	3	3.5	17	6.2	29	7.8	27	56.3
	Available	34	94.4	82	96.5	259	93.8	345	92.2	21	43.8

		Era									
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
		N	%	N	%	N	%	N	%	N	%	p
Lipid-lowering medication	No	4	100.0	1	50.0	34	79.1	129	86.6	20	95.2	
	Yes		0.0	1	50.0	9	20.9	20	13.4	1	4.8	

Data completeness		Era									
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
		N	%	N	%	N	%	N	%	N	%
Lipid-lowering medication	Missing	32	88.9	83	97.6	233	84.4	225	60.2	27	56.3
	Available	4	11.1	2	2.4	43	15.6	149	39.8	21	43.8

*=p<.05; **=p<.01; ***=p<.001

Exhibit 2-3 (continued)
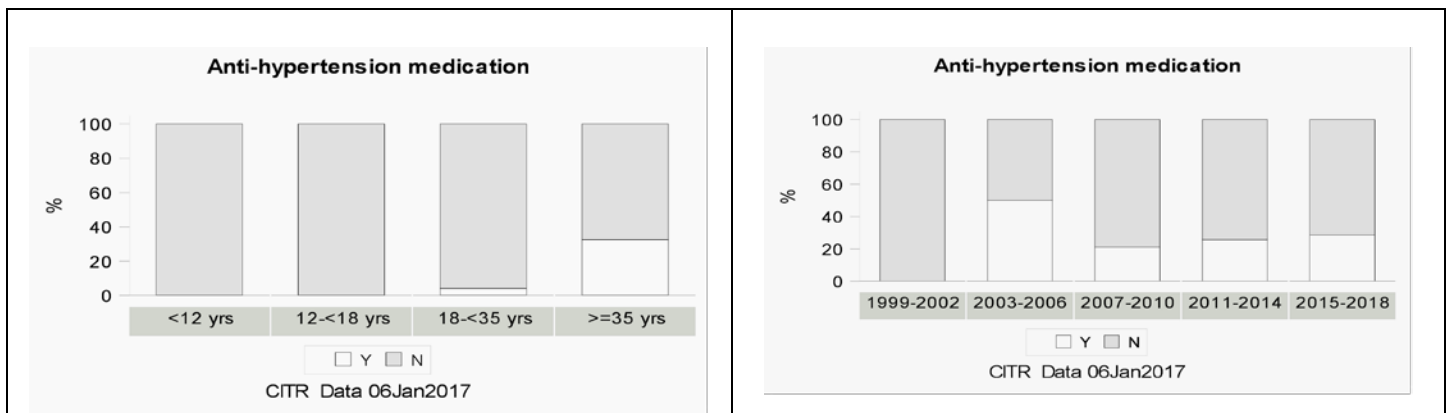**Recipient Diabetes Characteristics and Medical History**

		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Anti-hypertension medication	No	3	100.0	5	100.0	48	96.0	110	67.5	***
	Yes		0.0		0.0	2	4.0	53	32.5	

Data completeness		Age Group							
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs	
		N	%	N	%	N	%	N	%
Anti-hypertension medication	Missing	31	91.2	57	91.9	166	76.9	344	67.9
	Available	3	8.8	5	8.1	50	23.1	163	32.1

		Era									
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
		N	%	N	%	N	%	N	%	N	%	p
Anti-hypertension medication	No	4	100.0	1	50.0	34	79.1	112	74.2	15	71.4	
	Yes		0.0	1	50.0	9	20.9	39	25.8	6	28.6	

Data completeness		Era								
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
		N	%	N	%	N	%	N	%	N	%
Anti-hypertension medication	Missing	32	88.9	83	97.6	233	84.4	223	59.6	27	56.3
	Available	4	11.1	2	2.4	43	15.6	151	40.4	21	43.8

*=p<.05; **=p<.01; ***=p<.001

Exhibit 2-3 (continued)
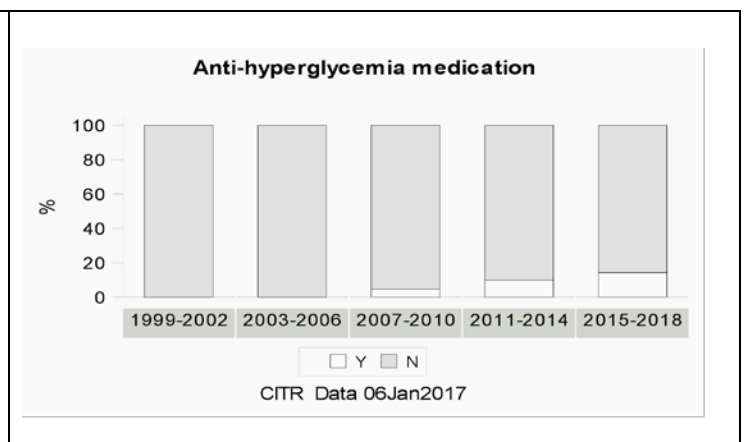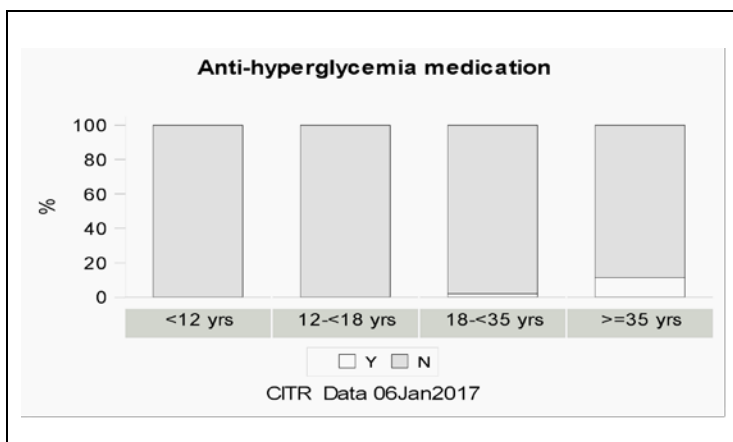**Recipient Diabetes Characteristics and Medical History**

		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Anti-hyperglycemia medication	No	3	100.0	5	100.0	49	98.0	149	88.7	
	Yes		0.0		0.0	1	2.0	19	11.3	

		Age Group								
Data completeness		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Anti-hyperglycemia medication	Missing	31	91.2	57	91.9	166	76.9	339	66.9	
	Available	3	8.8	5	8.1	50	23.1	168	33.1	

		Era									
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
		N	%	N	%	N	%	N	%	N	%	p
Anti-hyperglycemia medication	No	4	100.0	2	100.0	42	95.5	140	90.3	18	85.7	
	Yes		0.0		0.0	2	4.5	15	9.7	3	14.3	

		Era									
Data completeness		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
		N	%	N	%	N	%	N	%	N	%
Anti-hyperglycemia medication	Missing	32	88.9	83	97.6	232	84.1	219	58.6	27	56.3
	Available	4	11.1	2	2.4	44	15.9	155	41.4	21	43.8

*=p<.05; **=p<.01; ***=p<.001

Exhibit 2-3 (continued)
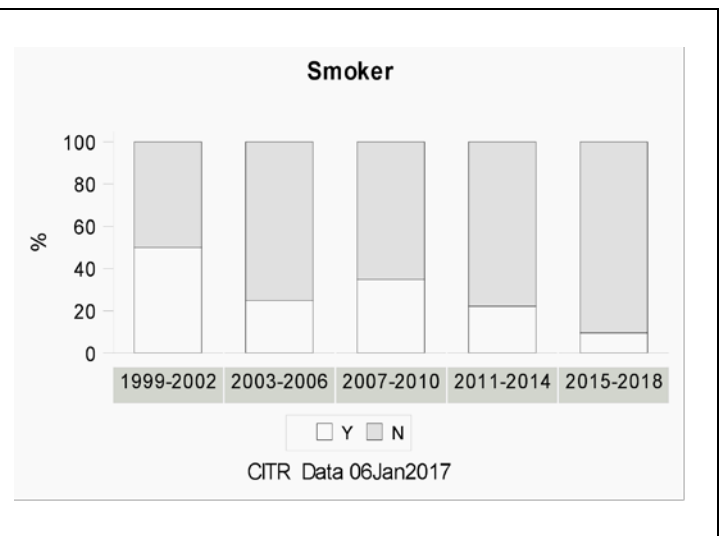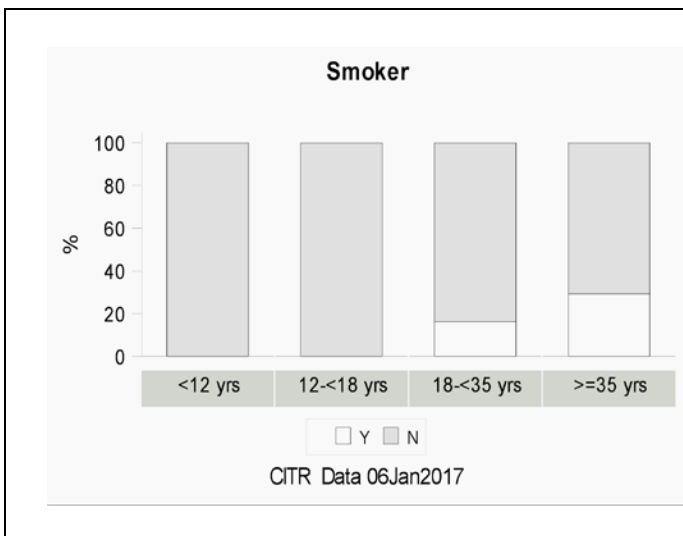## Recipient Diabetes Characteristics and Medical History

		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Smoker	No	3	100.0	5	100.0	52	83.9	145	70.7	
	Yes		0.0		0.0	10	16.1	60	29.3	

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Smoker	Missing	31	91.2	57	91.9	154	71.3	302	59.6	
	Available	3	8.8	5	8.1	62	28.7	205	40.4	

		Era									
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
		N	%	N	%	N	%	N	%	N	%	p
Smoker	No	1	50.0	9	75.0	56	65.1	120	77.9	19	90.5	
	Yes	1	50.0	3	25.0	30	34.9	34	22.1	2	9.5	

Data completeness		Era									
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
		N	%	N	%	N	%	N	%	N	%	
Smoker	Missing	34	94.4	73	85.9	190	68.8	220	58.8	27	56.3	
	Available	2	5.6	12	14.1	86	31.2	154	41.2	21	43.8	

*=p<.05; **=p<.01; ***=p<.001

Exhibit 2-3 (continued)
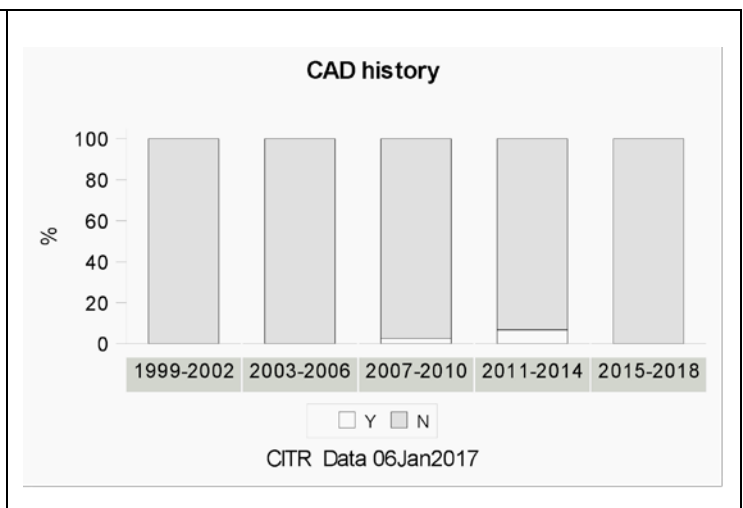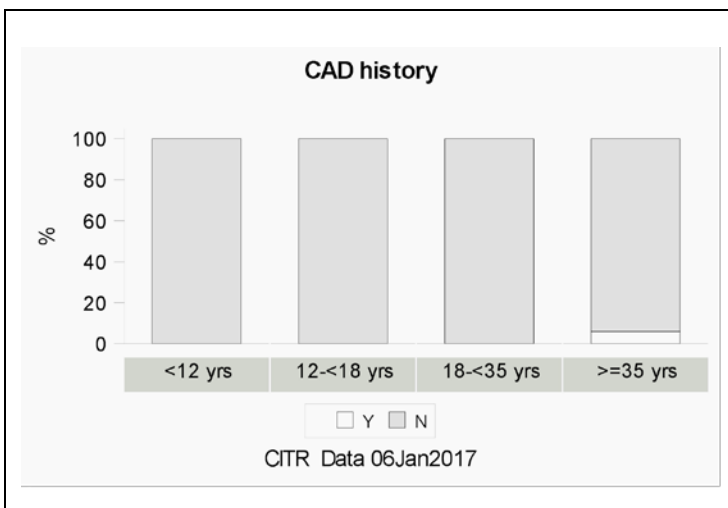**Recipient Diabetes Characteristics and Medical History**

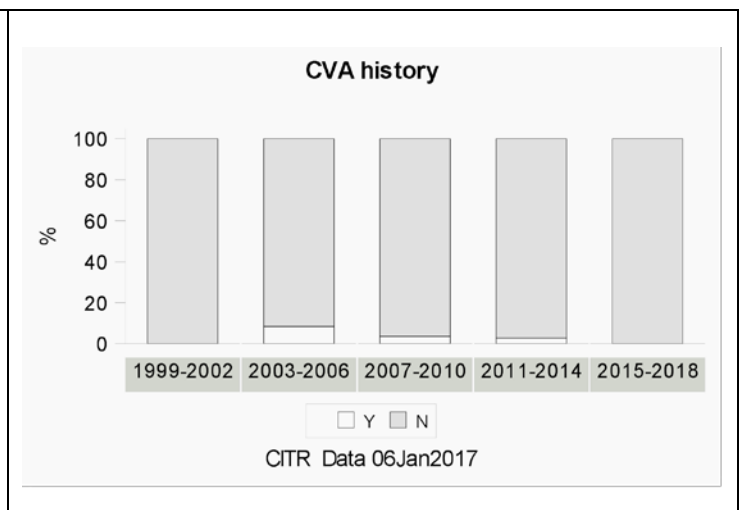|		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
CAD history	No	3	100.0	5	100.0	57	100.0	192	94.1	
	Yes		0.0		0.0		0.0	12	5.9	

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
CAD history	Missing	31	91.2	57	91.9	159	73.6	303	59.8	
	Available	3	8.8	5	8.1	57	26.4	204	40.2	

		Era									
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
		N	%	N	%	N	%	N	%	N	%	p
CAD history	No	4	100.0	12	100.0	82	97.6	138	93.2	21	100.0	
	Yes		0.0		0.0	2	2.4	10	6.8		0.0	

Data completeness		Era									
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
		N	%	N	%	N	%	N	%	N	%
CAD history	Missing	32	88.9	73	85.9	192	69.6	226	60.4	27	56.3
	Available	4	11.1	12	14.1	84	30.4	148	39.6	21	43.8

*=p<.05; **=p<.01; ***=p<.001

Exhibit 2-3 (continued)
Recipient Diabetes Characteristics and Medical History

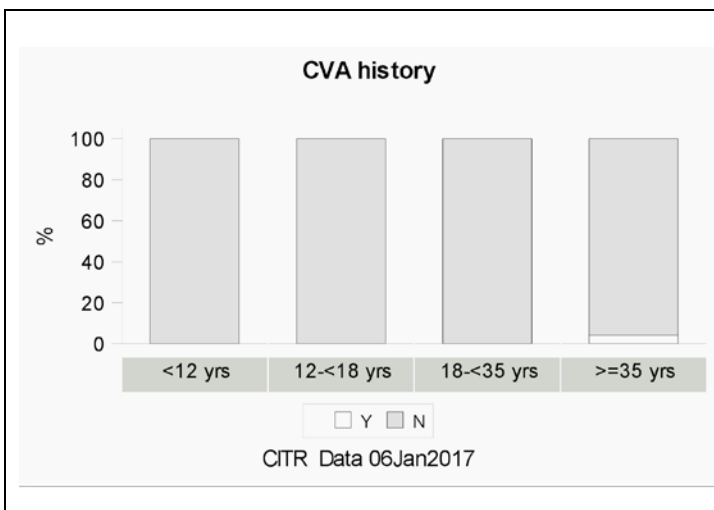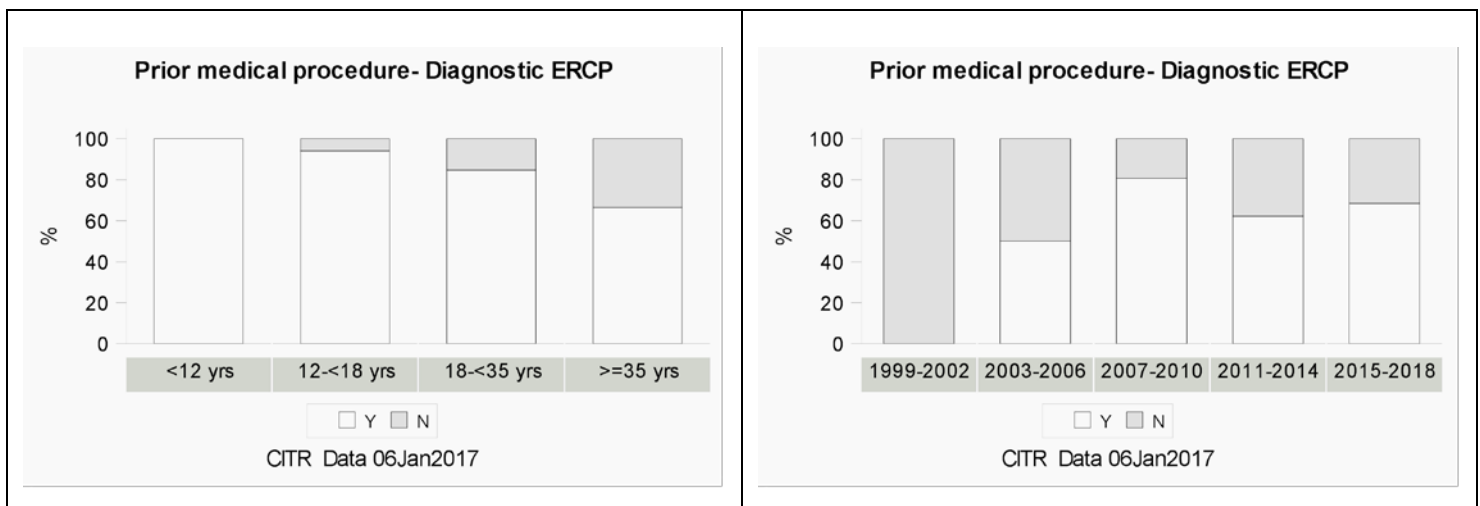|		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
CVA history	No	3	100.0	5	100.0	58	100.0	196	96.1	
	Yes		0.0		0.0		0.0	8	3.9	

		Age Group								
Data completeness		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
CVA history	Missing	31	91.2	57	91.9	158	73.1	303	59.8	
	Available	3	8.8	5	8.1	58	26.9	204	40.2	

		Era									
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
		N	%	N	%	N	%	N	%	N	%	p
CVA history	No	4	100.0	11	91.7	82	96.5	144	97.3	21	100.0	
	Yes		0.0	1	8.3	3	3.5	4	2.7		0.0	

		Era									
Data completeness		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
		N	%	N	%	N	%	N	%	N	%
CVA history	Missing	32	88.9	73	85.9	191	69.2	226	60.4	27	56.3
	Available	4	11.1	12	14.1	85	30.8	148	39.6	21	43.8

*=p<.05; **=p<.01; ***=p<.001

Exhibit 2-3 (continued)
Recipient Diabetes Characteristics and Medical History

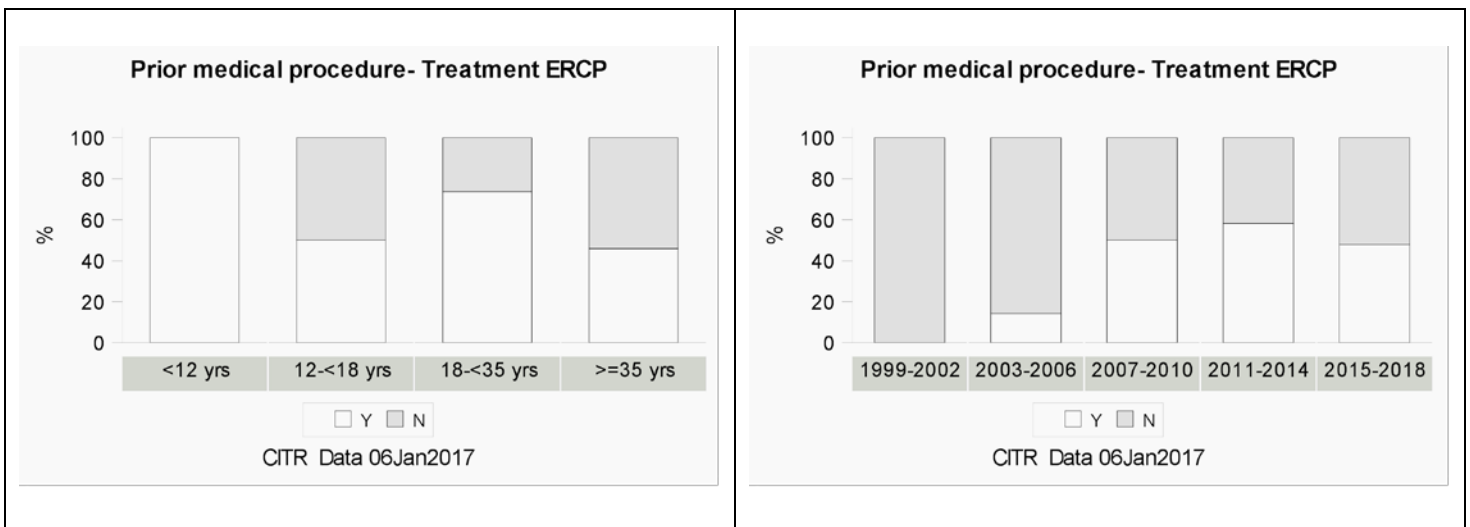|		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**p**
Prior medical procedure- Diagnostic ERCP	**No**		0.0	1	5.9	16	15.2	91	33.6	***
	Yes	4	100.0	16	94.1	89	84.8	180	66.4	

Header spanning: **Age Group**

Data completeness		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs	
		N	**%**	**N**	**%**	**N**	**%**	**N**	**%**
Prior medical procedure- Diagnostic ERCP	**Missing**	30	88.2	45	72.6	111	51.4	236	46.5
	Available	4	11.8	17	27.4	105	48.6	271	53.5

Header spanning: **Age Group**

		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		
		N	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**p**
Prior medical procedure- Diagnostic ERCP	**No**	3	100.0	5	50.0	46	19.3	48	37.8	6	31.6	***
	Yes		0.0	5	50.0	192	80.7	79	62.2	13	68.4	

Header spanning: **Era**

Data completeness		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
		N	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
Prior medical procedure- Diagnostic ERCP	**Missing**	33	91.7	75	88.2	38	13.8	247	66.0	29	60.4
	Available	3	8.3	10	11.8	238	86.2	127	34.0	19	39.6

Header spanning: **Era**

*=p<.05; **=p<.01; ***=p<.001

Exhibit 2-3 (continued)
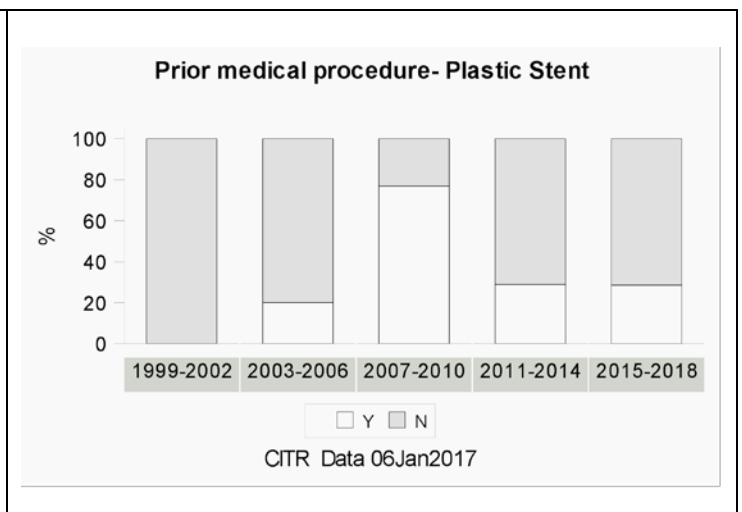**Recipient Diabetes Characteristics and Medical History**

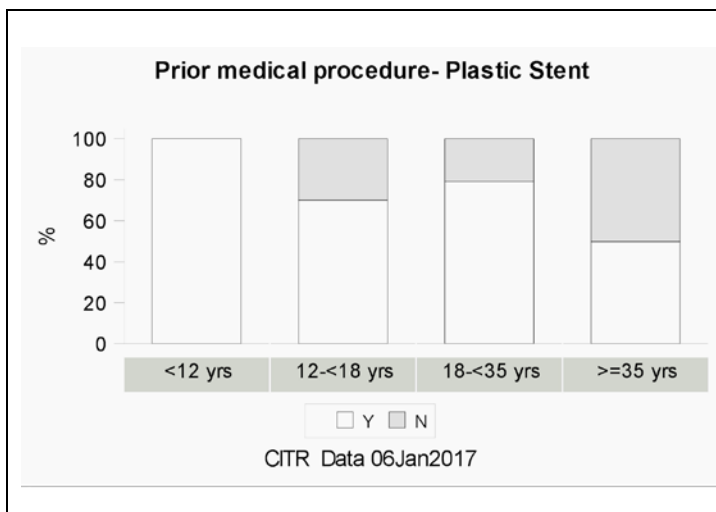|		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Prior medical procedure- Treatment ERCP	No		0.0	2	50.0	16	26.2	105	54.1	***
	Yes	2	100.0	2	50.0	45	73.8	89	45.9	

Data completeness		Age Group							
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs	
		N	%	N	%	N	%	N	%
Prior medical procedure- Treatment ERCP	Missing	32	94.1	58	93.5	155	71.8	313	61.7
	Available	2	5.9	4	6.5	61	28.2	194	38.3

		Era									
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
		N	%	N	%	N	%	N	%	N	%	p
Prior medical procedure- Treatment ERCP	No	3	100.0	6	85.7	41	50.0	61	41.8	12	52.2	*
	Yes		0.0	1	14.3	41	50.0	85	58.2	11	47.8	

Data completeness		Era								
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
		N	%	N	%	N	%	N	%	N	%
Prior medical procedure- Treatment ERCP	Missing	33	91.7	78	91.8	194	70.3	228	61.0	25	52.1
	Available	3	8.3	7	8.2	82	29.7	146	39.0	23	47.9

*=p<.05; **=p<.01; ***=p<.001

Exhibit 2-3 (continued)
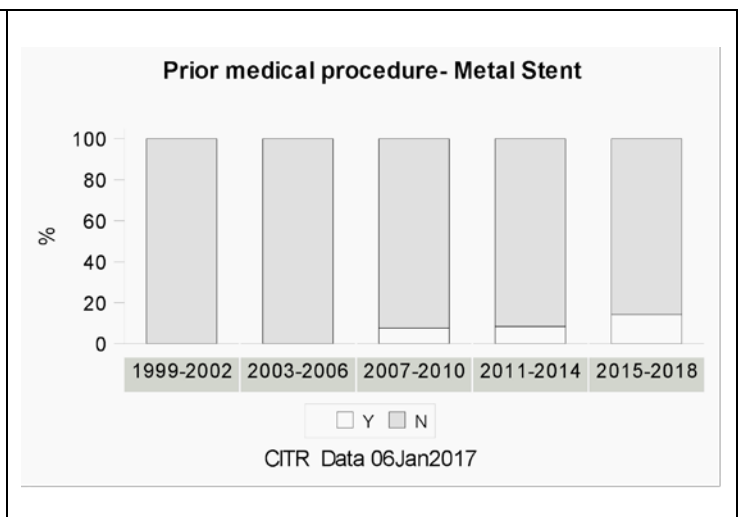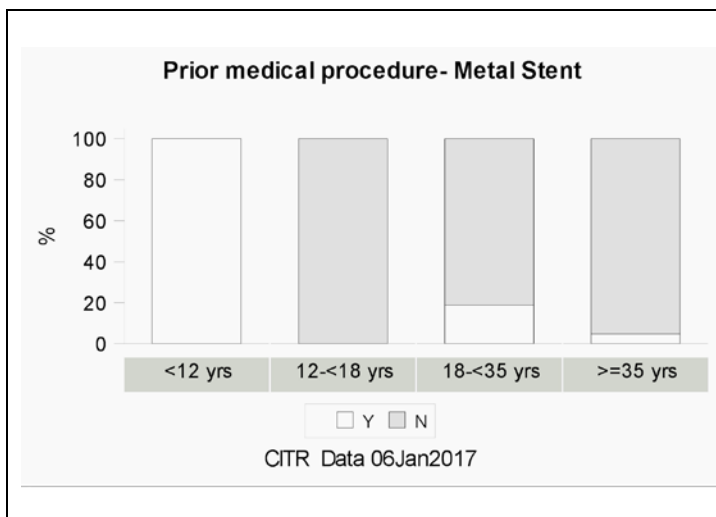**Recipient Diabetes Characteristics and Medical History**

		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Prior medical procedure- Plastic Stent	No		0.0	3	30.0	18	20.9	116	50.2	***
	Yes	1	100.0	7	70.0	68	79.1	115	49.8	

		Age Group							
Data completeness		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs	
		N	%	N	%	N	%	N	%
Prior medical procedure- Plastic Stent	Missing	33	97.1	52	83.9	130	60.2	276	54.4
	Available	1	2.9	10	16.1	86	39.8	231	45.6

		Era									
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
		N	%	N	%	N	%	N	%	N	%	p
Prior medical procedure- Plastic Stent	No	3	100.0	8	80.0	47	23.0	69	71.1	10	71.4	***
	Yes		0.0	2	20.0	157	77.0	28	28.9	4	28.6	

		Era								
Data completeness		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
		N	%	N	%	N	%	N	%	N	%
Prior medical procedure- Plastic Stent	Missing	33	91.7	75	88.2	72	26.1	277	74.1	34	70.8
	Available	3	8.3	10	11.8	204	73.9	97	25.9	14	29.2

*=p<.05; **=p<.01; ***=p<.001

Exhibit 2-3 (continued)
Recipient Diabetes Characteristics and Medical History

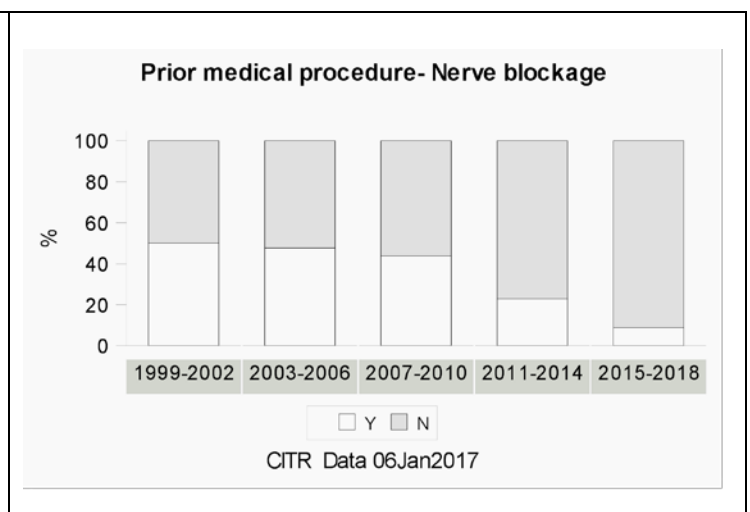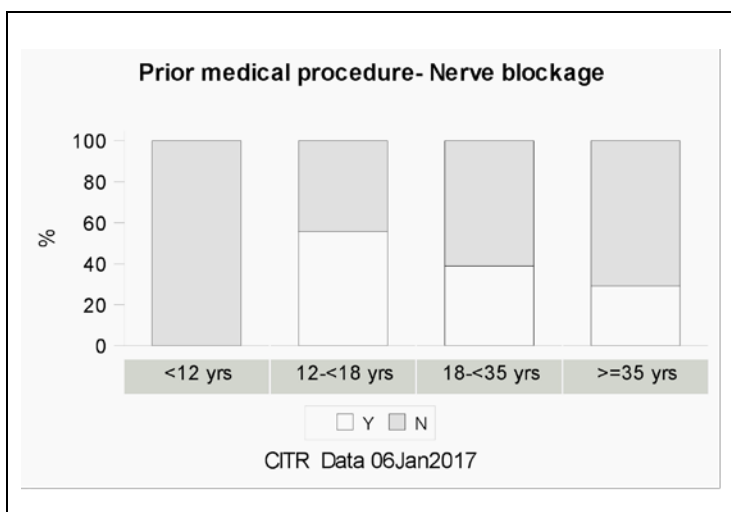|		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Prior medical procedure- Metal Stent	No		0.0	3	100.0	30	81.1	140	95.2	**
	Yes	1	100.0		0.0	7	18.9	7	4.8	

Data completeness		Age Group							
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs	
		N	%	N	%	N	%	N	%
Prior medical procedure- Metal Stent	Missing	33	97.1	59	95.2	179	82.9	360	71.0
	Available	1	2.9	3	4.8	37	17.1	147	29.0

		Era									
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
		N	%	N	%	N	%	N	%	N	%	p
Prior medical procedure- Metal Stent	No	3	100.0	9	100.0	61	92.4	88	91.7	12	85.7	
	Yes		0.0		0.0	5	7.6	8	8.3	2	14.3	

Data completeness		Era								
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
		N	%	N	%	N	%	N	%	N	%
Prior medical procedure- Metal Stent	Missing	33	91.7	76	89.4	210	76.1	278	74.3	34	70.8
	Available	3	8.3	9	10.6	66	23.9	96	25.7	14	29.2

*=p<.05; **=p<.01; ***=p<.001

Exhibit 2-3 (continued)
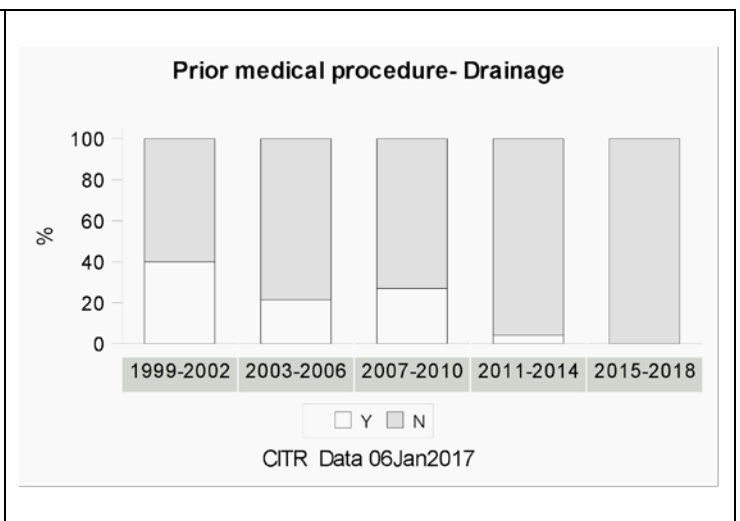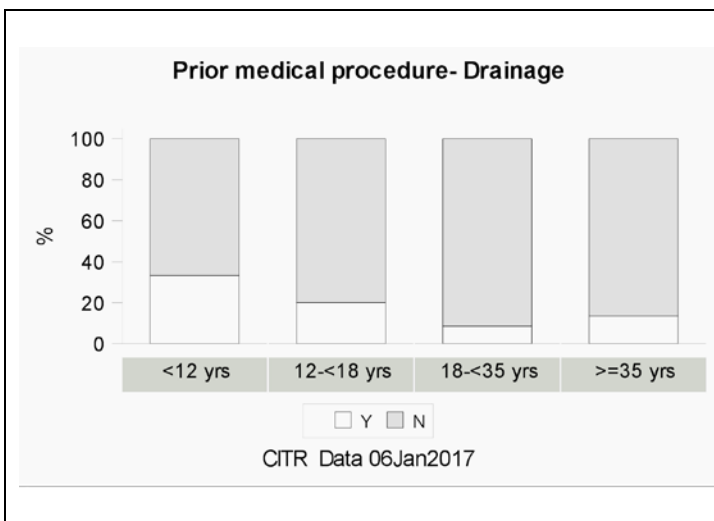**Recipient Diabetes Characteristics and Medical History**

		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Prior medical procedure- Nerve blockage	No	3	100.0	4	44.4	52	61.2	167	71.1	
	Yes		0.0	5	55.6	33	38.8	68	28.9	

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Prior medical procedure- Nerve blockage	Missing	31	91.2	53	85.5	131	60.6	272	53.6	
	Available	3	8.8	9	14.5	85	39.4	235	46.4	

		Era								
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		
		N	%	N	%	N	%	N	%	N	%	p
Prior medical procedure- Nerve blockage	No	3	50.0	11	52.4	72	56.3	119	77.3	21	91.3	***
	Yes	3	50.0	10	47.6	56	43.8	35	22.7	2	8.7	

Data completeness		Era								
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		
		N	%	N	%	N	%	N	%	N	%	
Prior medical procedure- Nerve blockage	Missing	30	83.3	64	75.3	148	53.6	220	58.8	25	52.1	
	Available	6	16.7	21	24.7	128	46.4	154	41.2	23	47.9	

*=p<.05; **=p<.01; ***=p<.001

Exhibit 2-3 (continued)
Recipient Diabetes Characteristics and Medical History

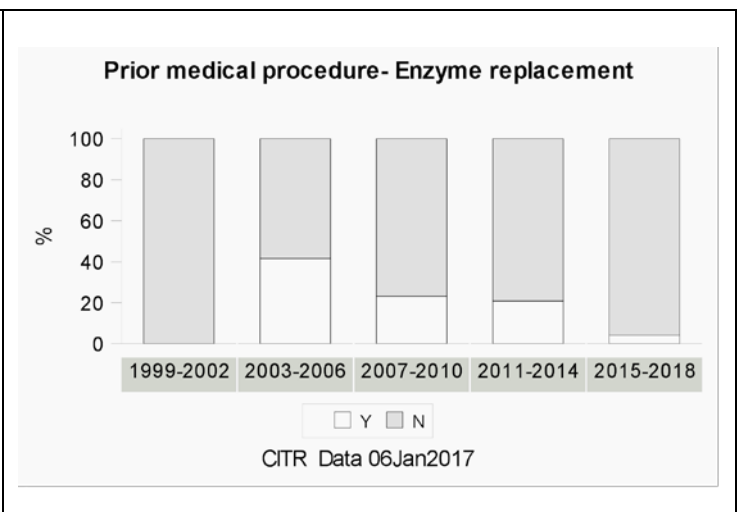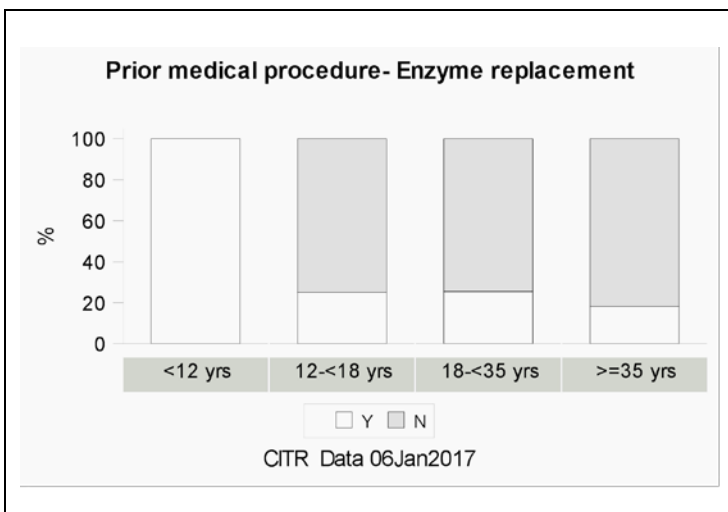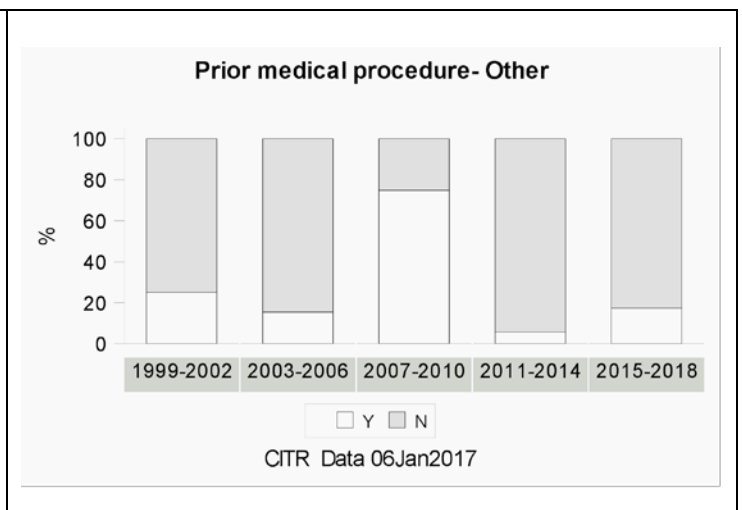|		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**p**
Prior medical procedure- Drainage	No	2	66.7	4	80.0	54	91.5	180	86.5	
	Yes	1	33.3	1	20.0	5	8.5	28	13.5	

Age Group

Data completeness		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	**%**	**N**	**%**	**N**	**%**	**N**	**%**	
Prior medical procedure- Drainage	Missing	31	91.2	57	91.9	157	72.7	299	59.0	
	Available	3	8.8	5	8.1	59	27.3	208	41.0	

Age Group

		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		
		N	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**p**
Prior medical procedure- Drainage	No	3	60.0	11	78.6	65	73.0	139	95.9	22	100.0	***
	Yes	2	40.0	3	21.4	24	27.0	6	4.1		0.0	

Era

Data completeness		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		
		N	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**	
Prior medical procedure- Drainage	Missing	31	86.1	71	83.5	187	67.8	229	61.2	26	54.2	
	Available	5	13.9	14	16.5	89	32.2	145	38.8	22	45.8	

Era

*=p<.05; **=p<.01; ***=p<.001

Exhibit 2-3 (continued)
Recipient Diabetes Characteristics and Medical History

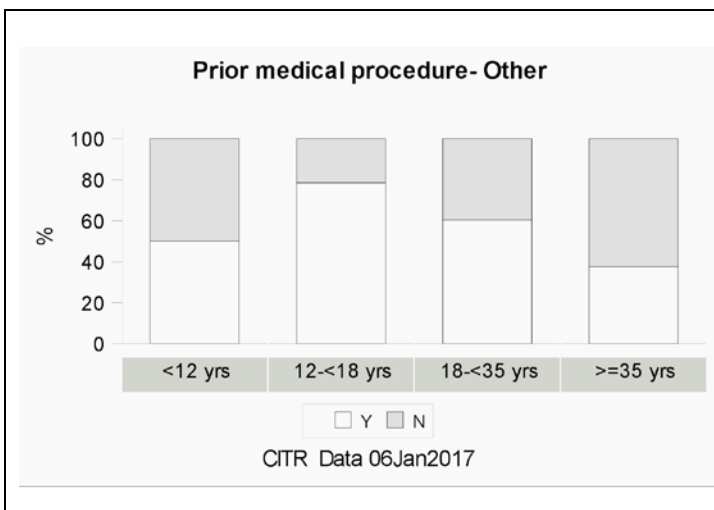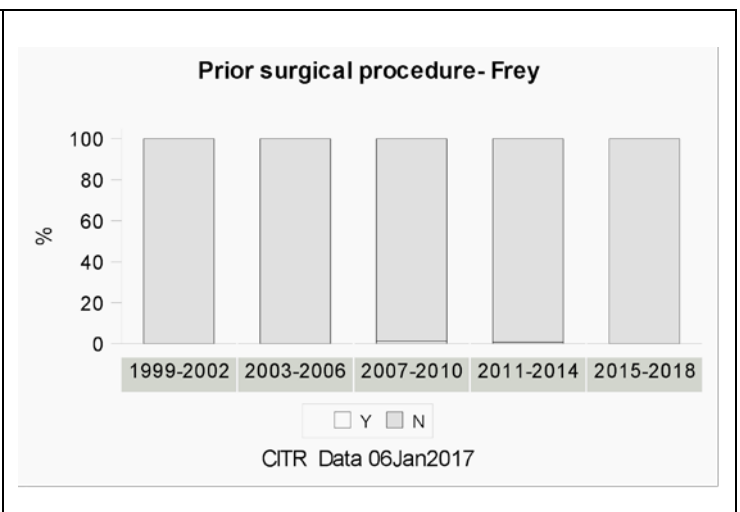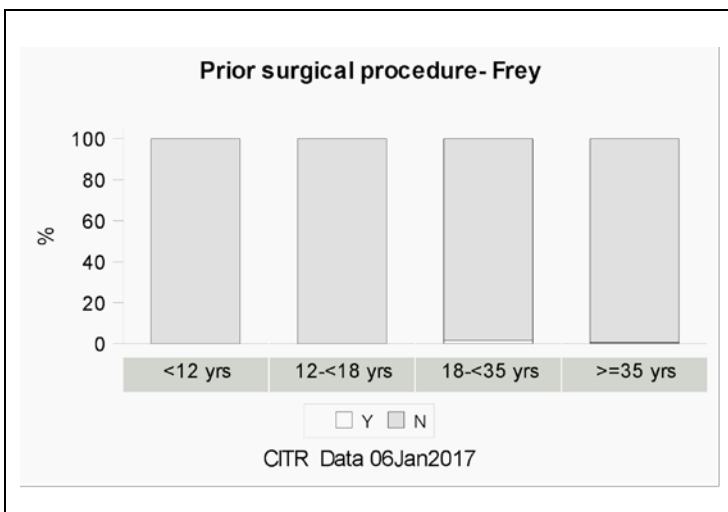|		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Prior medical procedure- Enzyme replacement	No		0.0	3	75.0	41	74.5	163	81.9	*
	Yes	3	100.0	1	25.0	14	25.5	36	18.1	

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Prior medical procedure- Enzyme replacement	Missing	31	91.2	58	93.5	161	74.5	308	60.7	
	Available	3	8.8	4	6.5	55	25.5	199	39.3	

		Era									
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
		N	%	N	%	N	%	N	%	N	%	p
Prior medical procedure- Enzyme replacement	No	3	100.0	7	58.3	60	76.9	114	79.2	23	95.8	
	Yes		0.0	5	41.7	18	23.1	30	20.8	1	4.2	

Data completeness		Era									
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
		N	%	N	%	N	%	N	%	N	%
Prior medical procedure- Enzyme replacement	Missing	33	91.7	73	85.9	198	71.7	230	61.5	24	50.0
	Available	3	8.3	12	14.1	78	28.3	144	38.5	24	50.0

*=p<.05; **=p<.01; ***=p<.001

Exhibit 2-3 (continued)
Recipient Diabetes Characteristics and Medical History

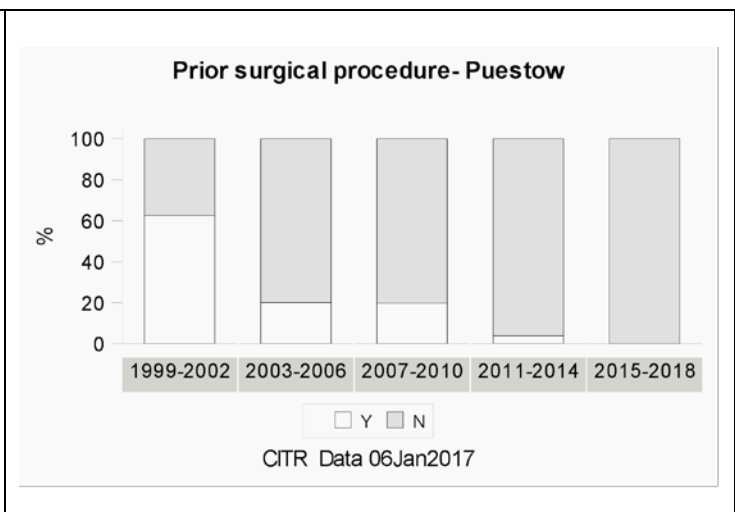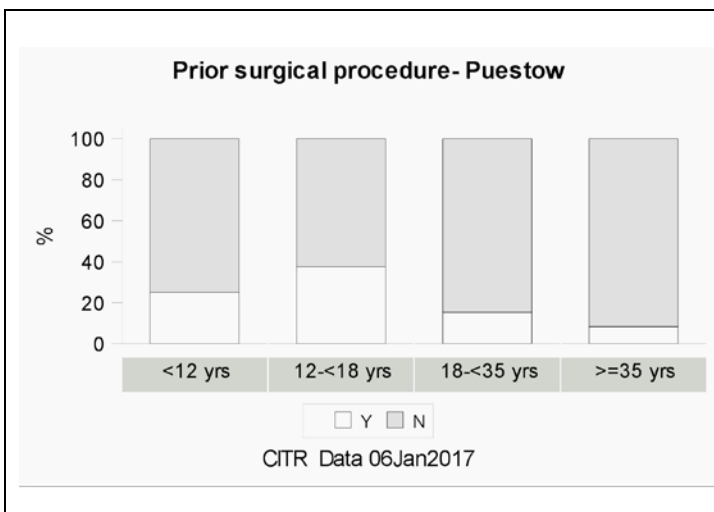|		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Prior medical procedure- Other	No	3	50.0	3	21.4	42	39.6	173	62.5	***
	Yes	3	50.0	11	78.6	64	60.4	104	37.5	

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Prior medical procedure- Other	Missing	28	82.4	48	77.4	110	50.9	230	45.4	
	Available	6	17.6	14	22.6	106	49.1	277	54.6	

		Era									
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
		N	%	N	%	N	%	N	%	N	%	p
Prior medical procedure- Other	No	3	75.0	11	84.6	56	25.1	132	94.3	19	82.6	***
	Yes	1	25.0	2	15.4	167	74.9	8	5.7	4	17.4	

Data completeness		Era									
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
		N	%	N	%	N	%	N	%	N	%
Prior medical procedure- Other	Missing	32	88.9	72	84.7	53	19.2	234	62.6	25	52.1
	Available	4	11.1	13	15.3	223	80.8	140	37.4	23	47.9

*=p<.05; **=p<.01; ***=p<.001

Exhibit 2-3 (continued)
Recipient Diabetes Characteristics and Medical History

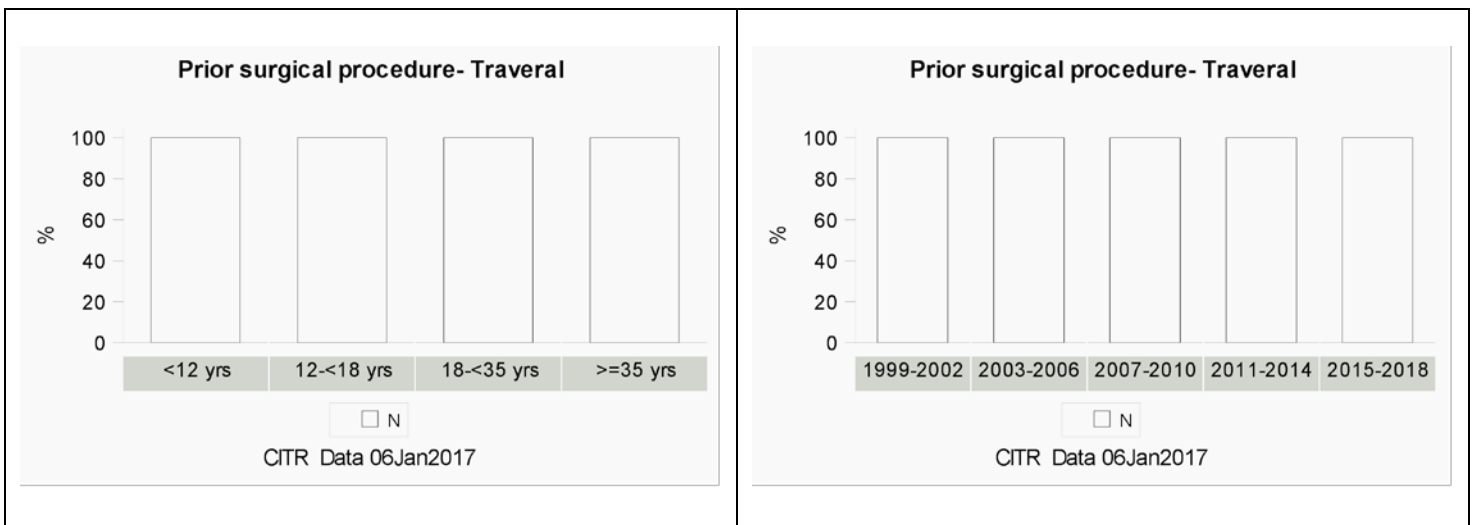|		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Prior surgical procedure- Frey	No	3	100.0	5	100.0	65	98.5	208	99.5	
	Yes		0.0		0.0	1	1.5	1	0.5	

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Prior surgical procedure- Frey	Missing	31	91.2	57	91.9	150	69.4	298	58.8	
	Available	3	8.8	5	8.1	66	30.6	209	41.2	

		Era										
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		
		N	%	N	%	N	%	N	%	N	%	p
Prior surgical procedure- Frey	No	3	100.0	12	100.0	85	98.8	157	99.4	24	100.0	
	Yes		0.0		0.0	1	1.2	1	0.6		0.0	

Data completeness		Era									
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
		N	%	N	%	N	%	N	%	N	%
Prior surgical procedure- Frey	Missing	33	91.7	73	85.9	190	68.8	216	57.8	24	50.0
	Available	3	8.3	12	14.1	86	31.2	158	42.2	24	50.0

*=p<.05; **=p<.01; ***=p<.001

Exhibit 2-3 (continued)
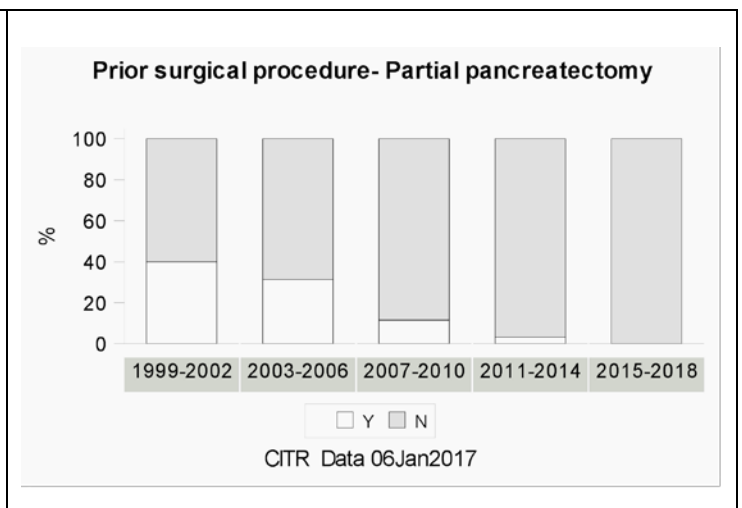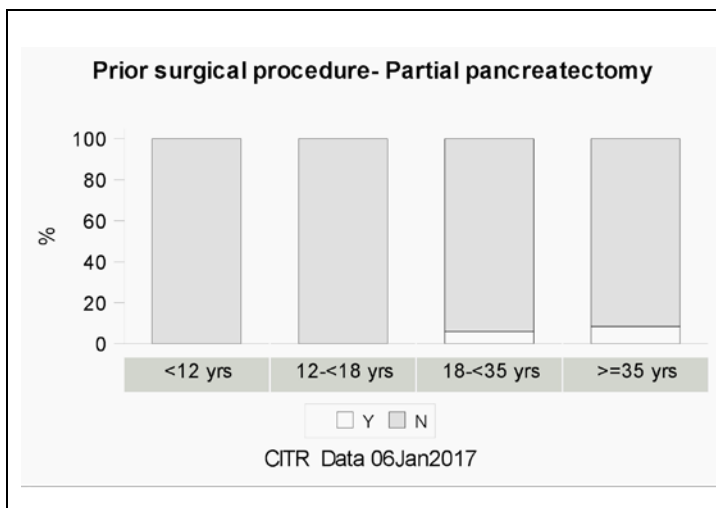**Recipient Diabetes Characteristics and Medical History**

		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Prior surgical procedure- Puestow	No	3	75.0	5	62.5	61	84.7	199	91.7	*
	Yes	1	25.0	3	37.5	11	15.3	18	8.3	

Data completeness		Age Group							
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs	
		N	%	N	%	N	%	N	%
Prior surgical procedure- Puestow	Missing	30	88.2	54	87.1	144	66.7	290	57.2
	Available	4	11.8	8	12.9	72	33.3	217	42.8

		Era									
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
		N	%	N	%	N	%	N	%	N	%	p
Prior surgical procedure- Puestow	No	3	37.5	12	80.0	77	80.2	152	96.2	24	100.0	***
	Yes	5	62.5	3	20.0	19	19.8	6	3.8		0.0	

Data completeness		Era								
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
		N	%	N	%	N	%	N	%	N	%
Prior surgical procedure- Puestow	Missing	28	77.8	70	82.4	180	65.2	216	57.8	24	50.0
	Available	8	22.2	15	17.6	96	34.8	158	42.2	24	50.0

*=p<.05; **=p<.01; ***=p<.001

Exhibit 2-3 (continued)
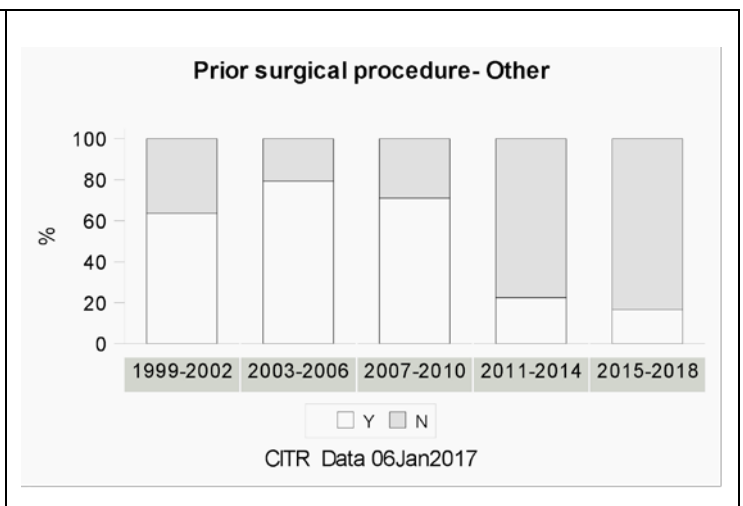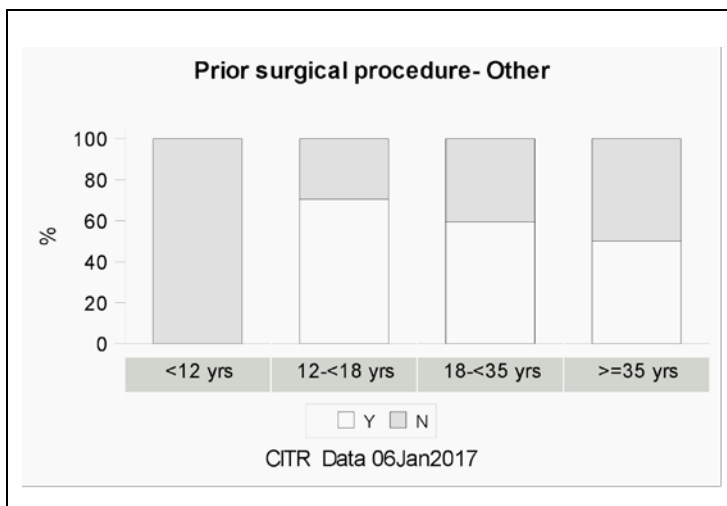**Recipient Diabetes Characteristics and Medical History**

		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Prior surgical procedure- Traveral	No	3	100.0	5	100.0	65	100.0	207	100.0	

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Prior surgical procedure- Traveral	Missing	31	91.2	57	91.9	151	69.9	300	59.2	
	Available	3	8.8	5	8.1	65	30.1	207	40.8	

		Era									
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
		N	%	N	%	N	%	N	%	N	%	p
Prior surgical procedure- Traveral	No	3	100.0	12	100.0	83	100.0	158	100.0	24	100.0	

Data completeness		Era									
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
		N	%	N	%	N	%	N	%	N	%
Prior surgical procedure- Traveral	Missing	33	91.7	73	85.9	193	69.9	216	57.8	24	50.0
	Available	3	8.3	12	14.1	83	30.1	158	42.2	24	50.0

*=p<.05; **=p<.01; ***=p<.001

Exhibit 2-3 (continued)
**Recipient Diabetes Characteristics and Medical History**

		Age Group								
		<12 yrs		**12-<18 yrs**		**18-<35 yrs**		**>=35 yrs**		
		N	%	N	%	N	%	N	%	p
Prior surgical procedure- partial pancreatectomy	No	3	100.0	5	100.0	64	94.1	197	91.6	
	Yes		0.0		0.0	4	5.9	18	8.4	

Data completeness		Age Group								
		<12 yrs		**12-<18 yrs**		**18-<35 yrs**		**>=35 yrs**		
		N	%	N	%	N	%	N	%	
Prior surgical procedure- partial pancreatectomy	Missing	31	91.2	57	91.9	148	68.5	292	57.6	
	Available	3	8.8	5	8.1	68	31.5	215	42.4	

		Era									
		1999-2002		**2003-2006**		**2007-2010**		**2011-2014**		**2015-2018**	
		N	%	N	%	N	%	N	%	N	%	p
Prior surgical procedure- partial pancreatectomy	No	3	60.0	11	68.8	77	88.5	154	96.9	24	100.0	***
	Yes	2	40.0	5	31.3	10	11.5	5	3.1		0.0	

Data completeness		Era									
		1999-2002		**2003-2006**		**2007-2010**		**2011-2014**		**2015-2018**	
		N	%	N	%	N	%	N	%	N	%
Prior surgical procedure- partial pancreatectomy	Missing	31	86.1	69	81.2	189	68.5	215	57.5	24	50.0
	Available	5	13.9	16	18.8	87	31.5	159	42.5	24	50.0

*=p<.05; **=p<.01; ***=p<.001

Exhibit 2-3 (continued)
Recipient Diabetes Characteristics and Medical History

		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Prior surgical procedure- Other	No	3	100.0	5	29.4	52	40.6	162	49.8	*
	Yes		0.0	12	70.6	76	59.4	163	50.2	

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Prior surgical procedure- Other	Missing	31	91.2	45	72.6	88	40.7	182	35.9	
	Available	3	8.8	17	27.4	128	59.3	325	64.1	

		Era									
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
		N	%	N	%	N	%	N	%	N	%	p
Prior surgical procedure- Other	No	4	36.4	12	20.7	65	29.0	121	77.6	20	83.3	***
	Yes	7	63.6	46	79.3	159	71.0	35	22.4	4	16.7	

Data completeness		Era									
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
		N	%	N	%	N	%	N	%	N	%	
Prior surgical procedure- Other	Missing	25	69.4	27	31.8	52	18.8	218	58.3	24	50.0	
	Available	11	30.6	58	68.2	224	81.2	156	41.7	24	50.0	

*=p<.05; **=p<.01; ***=p<.001

Exhibit 2-3 (continued)
Recipient Diabetes Characteristics and Medical History

		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Pancreatectomy performed	Yes	31	100.0	58	100.0	213	100.0	487	100.0	

		Age Group								
Data completeness		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Pancreatectomy performed	Missing	3	8.8	4	6.5	3	1.4	20	3.9	
	Available	31	91.2	58	93.5	213	98.6	487	96.1	

		Era									
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
		N	%	N	%	N	%	N	%	N	%	p
Pancreatectomy performed	Yes	36	100.0	82	100.0	260	100.0	365	100.0	46	100.0	

		Era									
Data completeness		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
		N	%	N	%	N	%	N	%	N	%
Pancreatectomy performed	Missing		0.0	3	3.5	16	5.8	9	2.4	2	4.2
	Available	36	100.0	82	96.5	260	94.2	365	97.6	46	95.8

*=p<.05; **=p<.01; ***=p<.001
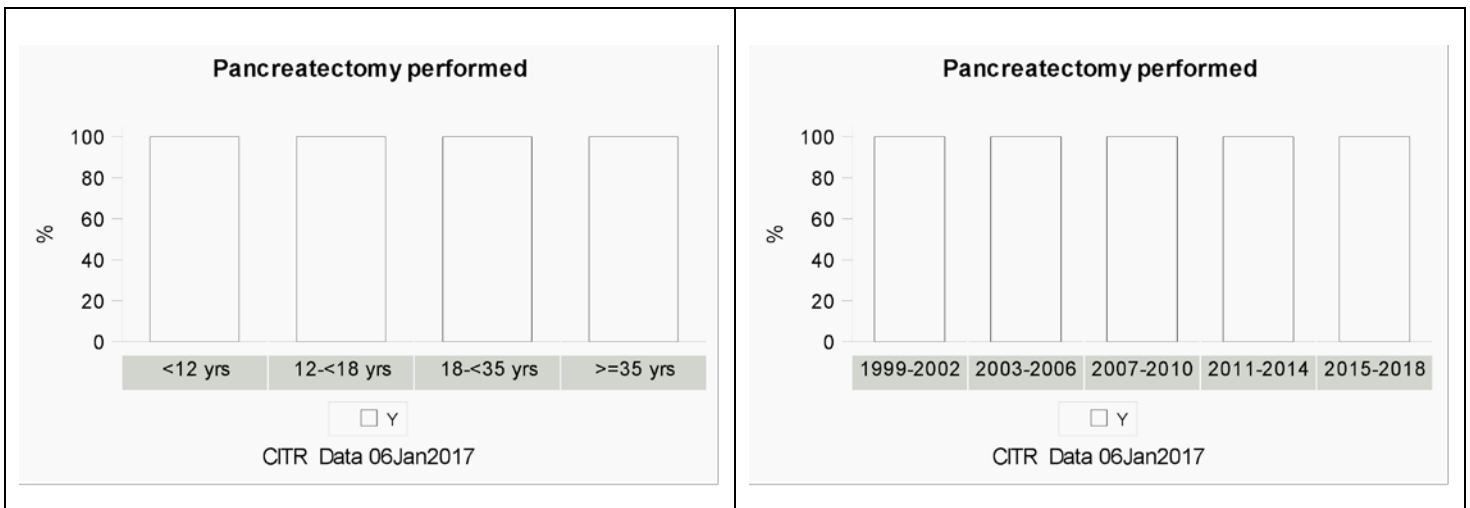
Exhibit 2-4
Recipient Pancreatectomy Information

		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Pancreatectomy type	Total or Completion(>=95%)	30	96.8	58	100.0	205	96.2	420	86.8	**
	Partial(<95%)	1	3.2		0.0	8	3.8	64	13.2	

		Age Group								
Data completeness		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Pancreatectomy type	Missing	3	8.8	4	6.5	3	1.4	23	4.5	
	Available	31	91.2	58	93.5	213	98.6	484	95.5	

		Era										
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		
		N	%	N	%	N	%	N	%	N	%	p
Pancreatectomy type	Total or Completion(>=95%)	23	63.9	67	81.7	236	91.1	344	94.8	43	93.5	***
	Partial(<95%)	13	36.1	15	18.3	23	8.9	19	5.2	3	6.5	

		Era									
Data completeness		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
		N	%	N	%	N	%	N	%	N	%
Pancreatectomy type	Missing		0.0	3	3.5	17	6.2	11	2.9	2	4.2
	Available	36	100.0	82	96.5	259	93.8	363	97.1	46	95.8

*=p<.05; **=p<.01; ***=p<.001

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Exhibit 2-4 (continued)
Recipient Pancreatectomy Information

		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Pancreatectomy for treating pancreatitis	No		0.0	3	5.2	9	4.2	74	15.8	***
	Yes	31	100.0	55	94.8	203	95.8	393	84.2	

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Pancreatectomy for treating pancreatitis	Missing	3	8.8	4	6.5	4	1.9	40	7.9	
	Available	31	91.2	58	93.5	212	98.1	467	92.1	

		Era										
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		
		N	%	N	%	N	%	N	%	N	%	p
Pancreatectomy for treating pancreatitis	No		0.0		0.0	23	9.2	53	14.6	10	21.7	***
	Yes	34	100.0	76	100.0	227	90.8	309	85.4	36	78.3	

Data completeness		Era									
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
		N	%	N	%	N	%	N	%	N	%
Pancreatectomy for treating pancreatitis	Missing	2	5.6	9	10.6	26	9.4	12	3.2	2	4.2
	Available	34	94.4	76	89.4	250	90.6	362	96.8	46	95.8

*=p<.05; **=p<.01; ***=p<.001

Exhibit 2-4 (continued)
Recipient Pancreatectomy Information

		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Pancreatectomy for treating cancer	No	4	100.0	9	100.0	49	100.0	138	80.2	***
	Yes		0.0		0.0		0.0	34	19.8	

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Pancreatectomy for treating cancer	Missing	30	88.2	53	85.5	167	77.3	335	66.1	
	Available	4	11.8	9	14.5	49	22.7	172	33.9	

		Era								
		2003-2006		2007-2010		2011-2014		2015-2018		
		N	%	N	%	N	%	N	%	p
Pancreatectomy for treating cancer	No	2	100.0	23	65.7	131	86.8	44	95.7	**
	Yes		0.0	12	34.3	20	13.2	2	4.3	

Data completeness		Era									
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
		N	%	N	%	N	%	N	%	N	%
Pancreatectomy for treating cancer	Missing	36	100.0	83	97.6	241	87.3	223	59.6	2	4.2
	Available		0.0	2	2.4	35	12.7	151	40.4	46	95.8

*=p<.05; **=p<.01; ***=p<.001

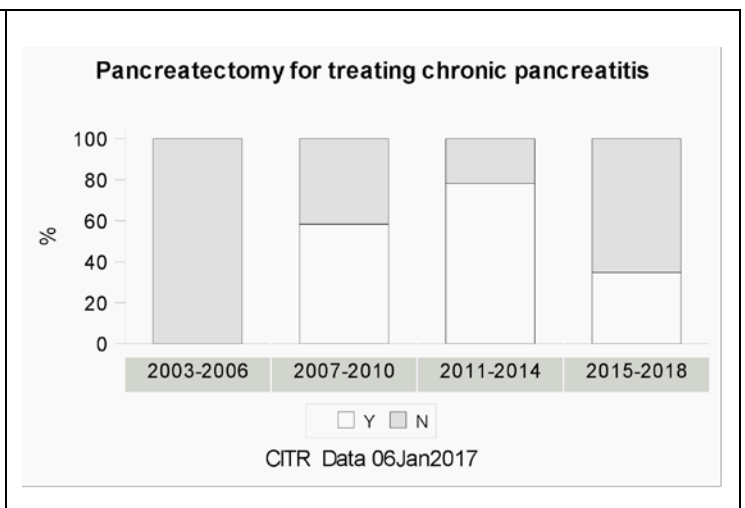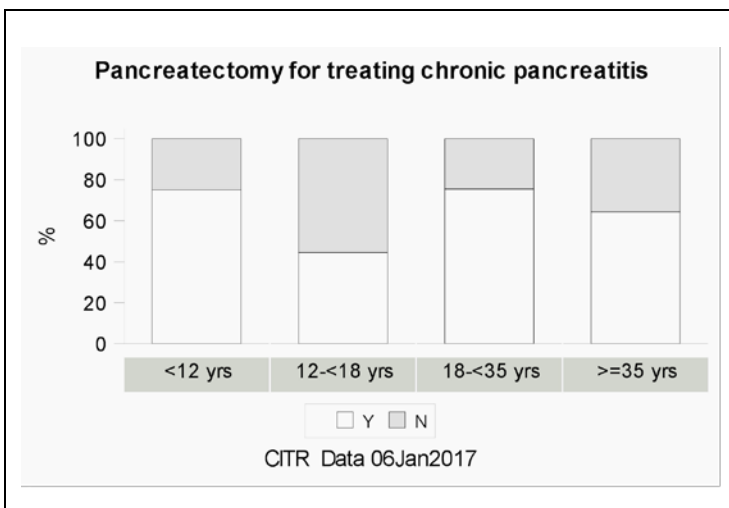**Exhibit 2-4 (continued)**
Recipient Pancreatectomy Information

		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Pancreatectomy for treating pancreatic pseudocysts	No	4	100.0	9	100.0	45	91.8	161	95.3	
	Yes		0.0		0.0	4	8.2	8	4.7	

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Pancreatectomy for treating pancreatic pseudocysts	Missing	30	88.2	53	85.5	167	77.3	338	66.7	
	Available	4	11.8	9	14.5	49	22.7	169	33.3	

		Era								
		2003-2006		2007-2010		2011-2014		2015-2018		
		N	%	N	%	N	%	N	%	p
Pancreatectomy for treating pancreatic pseudocysts	No	2	100.0	33	94.3	140	94.0	44	97.8	
	Yes		0.0	2	5.7	9	6.0	1	2.2	

Data completeness		Era									
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
		N	%	N	%	N	%	N	%	N	%
Pancreatectomy for treating pancreatic pseudocysts	Missing	36	100.0	83	97.6	241	87.3	225	60.2	3	6.3
	Available		0.0	2	2.4	35	12.7	149	39.8	45	93.8

*=p<.05; **=p<.01; ***=p<.001

Exhibit 2-4 (continued)
Recipient Pancreatectomy Information

		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Pancreatectomy for treating pancreatic cysts	No	4	100.0	9	100.0	49	100.0	166	97.1	
	Yes		0.0		0.0		0.0	5	2.9	

		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
Data completeness		N	%	N	%	N	%	N	%	
Pancreatectomy for treating pancreatic cysts	Missing	30	88.2	53	85.5	167	77.3	336	66.3	
	Available	4	11.8	9	14.5	49	22.7	171	33.7	

		2003-2006		2007-2010		2011-2014		2015-2018		
		N	%	N	%	N	%	N	%	p
Pancreatectomy for treating pancreatic cysts	No	2	100.0	33	97.1	148	98.0	45	97.8	
	Yes		0.0	1	2.9	3	2.0	1	2.2	

		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		
Data completeness		N	%	N	%	N	%	N	%	N	%	
Pancreatectomy for treating pancreatic cysts	Missing	36	100.0	83	97.6	242	87.7	223	59.6	2	4.2	
	Available		0.0	2	2.4	34	12.3	151	40.4	46	95.8	

*=p<.05; **=p<.01; ***=p<.001

Pancreatectomy for treating pancreatic cysts
(Age Group: <12 yrs, 12-<18 yrs, 18-<35 yrs, >=35 yrs)
Y N
CITR Data 06Jan2017

Pancreatectomy for treating pancreatic cysts
(Era: 2003-2006, 2007-2010, 2011-2014, 2015-2018)
Y N
CITR Data 06Jan2017

Exhibit 2-4 (continued)
Recipient Pancreatectomy Information

		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Pancreatectomy for treating tumors	No	4	100.0	9	100.0	48	98.0	167	97.1	
	Yes		0.0		0.0	1	2.0	5	2.9	

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Pancreatectomy for treating tumors	Missing	30	88.2	53	85.5	167	77.3	335	66.1	
	Available	4	11.8	9	14.5	49	22.7	172	33.9	

		Era								
		2003-2006		2007-2010		2011-2014		2015-2018		
		N	%	N	%	N	%	N	%	p
Pancreatectomy for treating tumors	No	2	100.0	34	97.1	147	97.4	45	97.8	
	Yes		0.0	1	2.9	4	2.6	1	2.2	

Data completeness		Era									
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
		N	%	N	%	N	%	N	%	N	%
Pancreatectomy for treating tumors	Missing	36	100.0	83	97.6	241	87.3	223	59.6	2	4.2
	Available		0.0	2	2.4	35	12.7	151	40.4	46	95.8

*=p<.05; **=p<.01; ***=p<.001

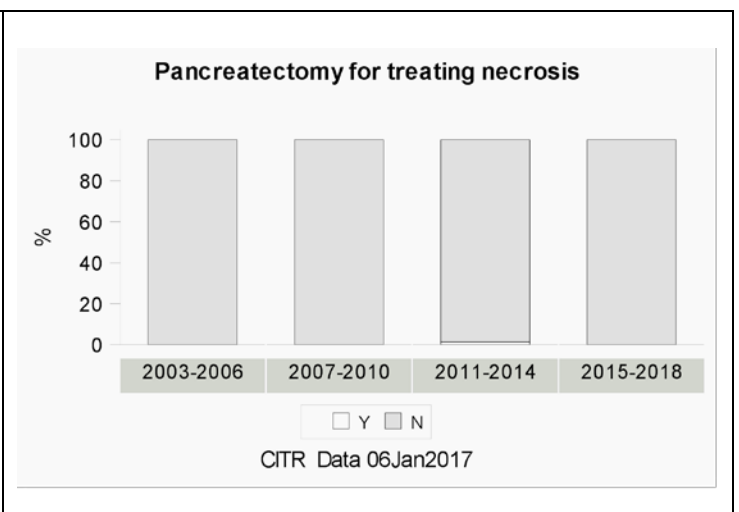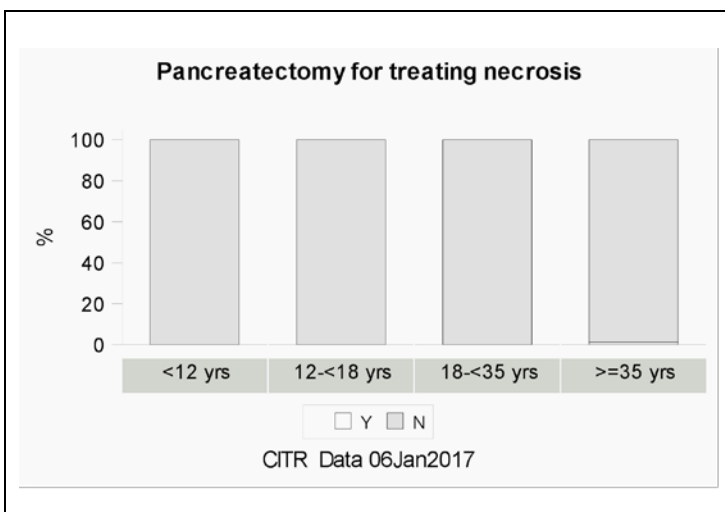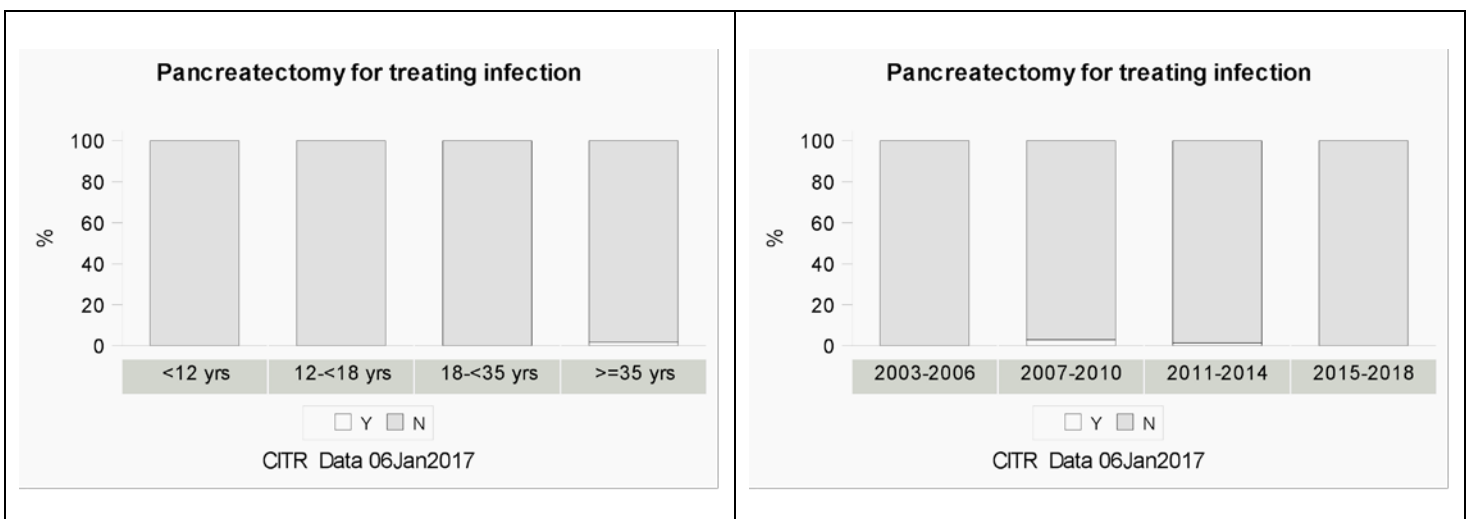**Exhibit 2-4 (continued)**
Recipient Pancreatectomy Information

		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Pancreatectomy for treating chronic pancreatitis	No	1	25.0	5	55.6	12	24.5	62	35.6	
	Yes	3	75.0	4	44.4	37	75.5	112	64.4	

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Pancreatectomy for treating chronic pancreatitis	Missing	30	88.2	53	85.5	167	77.3	333	65.7	
	Available	4	11.8	9	14.5	49	22.7	174	34.3	

		Era								
		2003-2006		2007-2010		2011-2014		2015-2018		
		N	%	N	%	N	%	N	%	p
Pancreatectomy for treating chronic pancreatitis	No	2	100.0	15	41.7	33	21.7	30	65.2	***
	Yes		0.0	21	58.3	119	78.3	16	34.8	

Data completeness		Era									
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
		N	%	N	%	N	%	N	%	N	%
Pancreatectomy for treating chronic pancreatitis	Missing	36	100.0	83	97.6	240	87.0	222	59.4	2	4.2
	Available		0.0	2	2.4	36	13.0	152	40.6	46	95.8

*=p<.05; **=p<.01; ***=p<.001

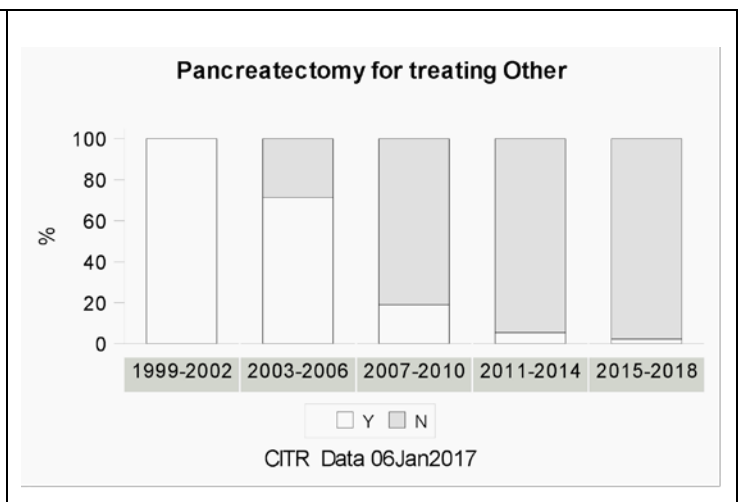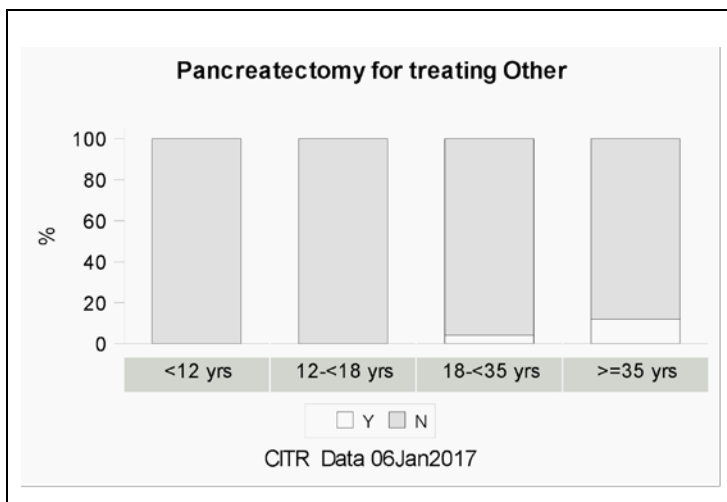**Exhibit 2-4 (continued)**
Recipient Pancreatectomy Information

		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Pancreatectomy for treating acute pancreatitis	No	2	50.0	9	100.0	41	82.0	154	89.5	
	Yes	2	50.0		0.0	9	18.0	18	10.5	

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Pancreatectomy for treating acute pancreatitis	Missing	30	88.2	53	85.5	166	76.9	335	66.1	
	Available	4	11.8	9	14.5	50	23.1	172	33.9	

		Era								
		2003-2006		2007-2010		2011-2014		2015-2018		
		N	%	N	%	N	%	N	%	p
Pancreatectomy for treating acute pancreatitis	No	2	100.0	35	100.0	127	83.6	42	91.3	*
	Yes		0.0		0.0	25	16.4	4	8.7	

Data completeness		Era									
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
		N	%	N	%	N	%	N	%	N	%
Pancreatectomy for treating acute pancreatitis	Missing	36	100.0	83	97.6	241	87.3	222	59.4	2	4.2
	Available		0.0	2	2.4	35	12.7	152	40.6	46	95.8

*=p<.05; **=p<.01; ***=p<.001

Exhibit 2-4 (continued)
Recipient Pancreatectomy Information

		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Pancreatectomy for treating trauma	No	4	100.0	9	100.0	48	98.0	171	99.4	
	Yes		0.0		0.0	1	2.0	1	0.6	

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Pancreatectomy for treating trauma	Missing	30	88.2	53	85.5	167	77.3	335	66.1	
	Available	4	11.8	9	14.5	49	22.7	172	33.9	

		Era								
		2003-2006		2007-2010		2011-2014		2015-2018		
		N	%	N	%	N	%	N	%	p
Pancreatectomy for treating trauma	No	2	100.0	35	100.0	150	99.3	45	97.8	
	Yes		0.0		0.0	1	0.7	1	2.2	

Data completeness		Era									
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
		N	%	N	%	N	%	N	%	N	%
Pancreatectomy for treating trauma	Missing	36	100.0	83	97.6	241	87.3	223	59.6	2	4.2
	Available		0.0	2	2.4	35	12.7	151	40.4	46	95.8
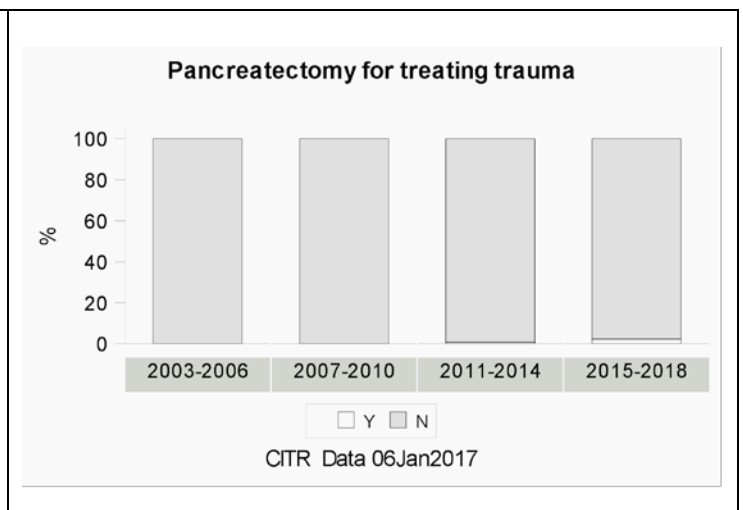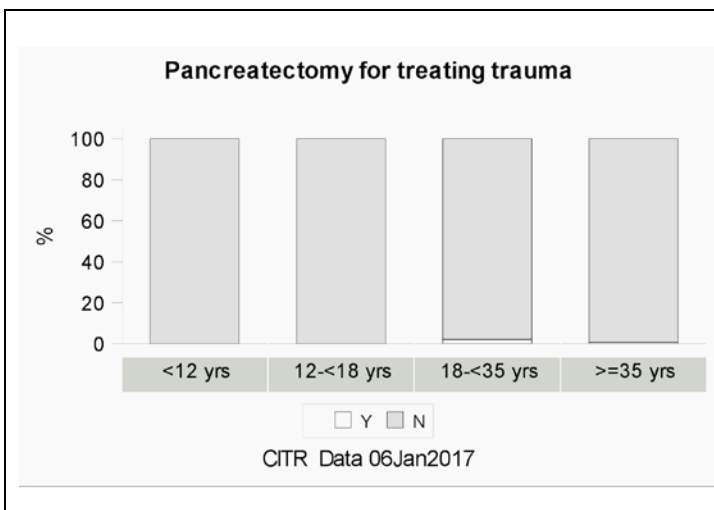
*=p<.05; **=p<.01; ***=p<.001

Exhibit 2-4 (continued)
Recipient Pancreatectomy Information

		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Pancreatectomy for treating necrosis	No	4	100.0	9	100.0	49	100.0	171	98.8	
	Yes		0.0		0.0		0.0	2	1.2	

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Pancreatectomy for treating necrosis	Missing	30	88.2	53	85.5	167	77.3	334	65.9	
	Available	4	11.8	9	14.5	49	22.7	173	34.1	

		Era								
		2003-2006		2007-2010		2011-2014		2015-2018		
		N	%	N	%	N	%	N	%	p
Pancreatectomy for treating necrosis	No	2	100.0	35	100.0	150	98.7	46	100.0	
	Yes		0.0		0.0	2	1.3		0.0	

Data completeness		Era										
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		
		N	%	N	%	N	%	N	%	N	%	
Pancreatectomy for treating necrosis	Missing	36	100.0	83	97.6	241	87.3	222	59.4	2	4.2	
	Available		0.0	2	2.4	35	12.7	152	40.6	46	95.8	

*=p<.05; **=p<.01; ***=p<.001

Exhibit 2-4 (continued)
Recipient Pancreatectomy Information

		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Pancreatectomy for treating infection	No	4	100.0	9	100.0	49	100.0	169	98.3	
	Yes		0.0		0.0		0.0	3	1.7	

		Age Group								
Data completeness		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Pancreatectomy for treating infection	Missing	30	88.2	53	85.5	167	77.3	335	66.1	
	Available	4	11.8	9	14.5	49	22.7	172	33.9	

		Era								
		2003-2006		2007-2010		2011-2014		2015-2018		
		N	%	N	%	N	%	N	%	p
Pancreatectomy for treating infection	No	2	100.0	34	97.1	149	98.7	46	100.0	
	Yes		0.0	1	2.9	2	1.3		0.0	

		Era										
Data completeness		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		
		N	%	N	%	N	%	N	%	N	%	
Pancreatectomy for treating infection	Missing	36	100.0	83	97.6	241	87.3	223	59.6	2	4.2	
	Available		0.0	2	2.4	35	12.7	151	40.4	46	95.8	

*=p<.05; **=p<.01; ***=p<.001

Exhibit 2-4 (continued)
Recipient Pancreatectomy Information

		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Pancreatectomy for treating Other	No	4	100.0	9	100.0	48	96.0	162	88.0	
	Yes		0.0		0.0	2	4.0	22	12.0	

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Pancreatectomy for treating Other	Missing	30	88.2	53	85.5	166	76.9	323	63.7	
	Available	4	11.8	9	14.5	50	23.1	184	36.3	

		Era										
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		
		N	%	N	%	N	%	N	%	N	%	p
Pancreatectomy for treating Other	No		0.0	2	28.6	34	81.0	142	94.7	45	97.8	***
	Yes	2	100.0	5	71.4	8	19.0	8	5.3	1	2.2	

Data completeness		Era										
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		
		N	%	N	%	N	%	N	%	N	%	
Pancreatectomy for treating Other	Missing	34	94.4	78	91.8	234	84.8	224	59.9	2	4.2	
	Available	2	5.6	7	8.2	42	15.2	150	40.1	46	95.8	

*=p<.05; **=p<.01; ***=p<.001

Exhibit 2-4 (continued)
Recipient Pancreatectomy Information

	Age Group												
	<12 yrs			12-<18 yrs			18-<35 yrs			>=35 yrs			
	N	Mean	SE	N	Mean	SE	N	Mean	SE	N	Mean	SE	p
Pancreatitis duration (yrs)	28	4.3	0.6	53	5.9	0.6	172	6.8	0.5	320	6.7	0.4	

	Era															
	1999-2002			2003-2006			2007-2010			2011-2014			2015-2018			
	N	Mean	SE	N	Mean	SE	N	Mean	SE	N	Mean	SE	N	Mean	SE	p
Pancreatitis duration (yrs)	25	7.0	1.0	68	7.2	0.7	201	6.7	0.4	251	6.0	0.4	28	7.9	1.2	

*=p<.05; **=p<.01; ***=p<.001

Pancreatitis duration (yrs) — by Age Group. CITR Data 06Jan2017

Pancreatitis duration (yrs) — by Era. CITR Data 06Jan2017

Exhibit 2-4 (continued)
Recipient Pancreatectomy Information

		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Pancreatitis etiology	Alcohol/Drug induced		0.0		0.0	8	4.1	35	10.0	***
	Biliary		0.0		0.0	5	2.6	13	3.7	
	Cystic Fibrosis		0.0	2	3.8	8	4.1	8	2.3	
	Idiopathic	5	16.7	10	18.9	63	32.5	126	35.9	
	Idiopathic (Pancreas divisum)	1	3.3	1	1.9	28	14.4	60	17.1	
	Sphincter of Oddi Dysfunction (SOD)		0.0	1	1.9	27	13.9	63	17.9	
	Trauma		0.0		0.0	3	1.5	1	0.3	
	Other		0.0	1	1.9	9	4.6	27	7.7	
	Familial	24	80.0	38	71.7	43	22.2	18	5.1	

		Age Group								
Data completeness		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Pancreatitis etiology	Missing	4	11.8	9	14.5	22	10.2	156	30.8	
	Available	30	88.2	53	85.5	194	89.8	351	69.2	

		Era										
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		
		N	%	N	%	N	%	N	%	N	%	p
Pancreatitis etiology	Alcohol/Drug induced	7	22.6	10	14.5	11	5.0	14	5.1	1	3.1	***
	Biliary	3	9.7	2	2.9	7	3.2	5	1.8	1	3.1	
	Cystic Fibrosis	1	3.2	2	2.9	11	5.0	3	1.1	1	3.1	
	Idiopathic	12	38.7	35	50.7	86	39.1	64	23.2	7	21.9	
	Idiopathic (Pancreas divisum)	6	19.4	8	11.6	31	14.1	41	14.9	4	12.5	
	Sphincter of Oddi Dysfunction (SOD)		0.0	7	10.1	42	19.1	39	14.1	3	9.4	
	Trauma		0.0		0.0		0.0	4	1.4		0.0	
	Other		0.0	2	2.9	11	5.0	21	7.6	3	9.4	
	Familial	2	6.5	3	4.3	21	9.5	85	30.8	12	37.5	

		Era									
Data completeness		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018	
		N	%	N	%	N	%	N	%	N	%
Pancreatitis etiology	Missing	5	13.9	16	18.8	56	20.3	98	26.2	16	33.3
	Available	31	86.1	69	81.2	220	79.7	276	73.8	32	66.7

*=p<.05; **=p<.01; ***=p<.001

Exhibit 2-4 (continued)
Recipient Pancreatectomy Information

Pancreatitis etiology

Legend: Alcohol/Drug induced, Biliary, Cystic Fibrosis, Idiopathic, Idiopathic (Pancreas divisum), Sphincter of Oddi Dysfunction (SOD), Trauma, Other, Familial

CITR Data 06Jan2017

Pancreatitis etiology

Legend: Alcohol/Drug induced, Biliary, Cystic Fibrosis, Idiopathic, Idiopathic (Pancreas divisum), Sphincter of Oddi Dysfunction (SOD), Trauma, Other, Familial

CITR Data 06Jan2017

Exhibit 2-4 (continued)
Recipient Pancreatectomy Information

Pancreatitis etiology

Era

2015-2018

2011-2014

2007-2010

2003-2006

1999-2002

| <12 yrs | 12-<18 yrs | 18-<35 yrs | >=35 yrs |

Age Group

Alcohol/Drug induced	Biliary		Cystic Fibrosis
Idiopathic	Idiopathic (Pancreas divisum)		Sphincter of Oddi Dysfunction (SOD)
Trauma	Other		Familial

CITR Data 06Jan2017

Exhibit 2-5
Recipient Laboratory Values at First Infusion

	Age Group											
	<12 yrs			12-<18 yrs			18-<35 yrs			>=35 yrs		
	N	Mean	SE	N	Mean	SE	N	Mean	SE	N	Mean	SE	p
HbA1c (%)	31	5.24	0.07	49	5.31	0.06	164	5.24	0.05	370	5.61	0.04	***
Basal C-Peptide (ng/mL)	29	1.36	0.21	47	1.90	0.14	167	2.25	0.11	379	2.12	0.07	*
Fasting blood glucose (mg/dL)	25	86.52	1.68	34	87.35	1.58	102	93.88	2.24	235	98.33	1.51	**
ALT (U/L)	3	17.00	1.00	4	26.00	4.42	65	41.88	5.10	222	40.58	3.50	
AST (U/L)	3	28.00	4.51	3	22.00	2.65	65	33.23	3.60	223	35.90	2.94	
Alkaline phosphatase (U/L)	3	270.00	81.84	4	126.50	14.84	65	87.03	5.26	218	99.74	4.25	***
Total bilirubin (mg/dL)	3	0.40	0.12	4	0.42	0.09	65	0.56	0.06	219	0.70	0.07	
Total cholesterol (mg/dL)	0	-	-	0	-	-	15	155.60	8.58	37	187.59	7.42	*
HDL (mg/dL)	0	-	-	0	-	-	15	37.80	3.24	35	48.06	3.41	
LDL (mg/dL)	0	-	-	0	-	-	14	81.71	7.15	26	115.54	7.95	**
Triglycerides (mg/dL)	0	-	-	0	-	-	18	167.56	24.25	43	120.60	12.62	
Serum creatinine (mg/dL)	3	0.53	0.07	4	0.58	0.06	69	0.81	0.05	225	0.82	0.02	
eGFR-CKD (mL/min/1.73m^2)	3	160.51	13.48	4	145.56	8.66	69	113.42	2.53	225	94.02	1.28	***

	Era														
	1999-2002			2003-2006			2007-2010			2011-2014			2015-2018		
	N	Mean	SE	N	Mean	SE	N	Mean	SE	N	Mean	SE	N	Mean	SE	p
HbA1c (%)	1	5.00	-	26	5.25	0.08	226	5.44	0.04	340	5.48	0.04	21	5.83	0.18	*
Basal C-Peptide (ng/mL)	4	1.35	0.33	17	2.57	0.44	231	2.23	0.10	350	1.97	0.07	20	2.87	0.35	**
Fasting blood glucose (mg/dL)	0	-	-	13	92.69	1.78	52	96.07	3.03	314	94.74	1.26	17	109.94	3.94	*
ALT (U/L)	4	81.75	32.59	14	40.50	11.12	89	40.55	5.50	164	39.84	3.94	23	36.87	5.67	
AST (U/L)	4	36.50	9.04	14	37.21	10.26	89	40.48	5.64	165	32.47	2.73	22	31.23	3.84	
Alkaline phosphatase (U/L)	4	97.75	33.50	13	108.15	20.03	87	95.07	4.79	163	98.72	5.23	23	111.17	16.49	
Total bilirubin (mg/dL)	4	0.56	0.17	13	0.62	0.08	88	0.70	0.08	163	0.66	0.08	23	0.58	0.09	
Total cholesterol (mg/dL)	2	193.00	50.00	0	-	-	9	184.78	22.39	37	175.30	6.21	4	185.00	22.44	
HDL (mg/dL)	2	44.50	9.50	0	-	-	9	50.89	8.16	35	44.34	2.97	4	37.50	9.54	
LDL (mg/dL)	0	-	-	0	-	-	8	104.00	25.78	30	101.53	4.46	2	135.00	46.00	
Triglycerides (mg/dL)	3	75.67	31.69	1	297.00	-	10	111.20	34.82	43	140.77	13.47	4	128.25	27.13	
Serum creatinine (mg/dL)	4	0.76	0.05	13	0.82	0.07	92	0.81	0.04	169	0.81	0.02	23	0.80	0.06	
eGFR-CKD (mL/min/1.73m^2)	4	111.91	2.42	13	96.11	4.82	92	98.54	2.31	169	100.26	1.74	23	101.60	6.09	

*=p<.05; **=p<.01; ***=p<.001

Exhibit 2-5 (continued)
Recipient Laboratory Values at First Infusion

Exhibit 2-5 (continued)
Recipient Laboratory Values at First Infusion

Exhibit 2-5 (continued)
Recipient Laboratory Values at First Infusion

Total bilirubin (mg/dL) — by Age Group and by Era

Total cholesterol (mg/dL) — by Age Group and by Era

HDL (mg/dL) — by Age Group and by Era

Exhibit 2-5 (continued)
Recipient Laboratory Values at First Infusion

LDL (mg/dL) — by Age Group (<12 yrs, 12-<18 yrs, 18-<35 yrs, >=35 yrs); CITR Data 06Jan2017

LDL (mg/dL) — by Era (1999-2002, 2003-2006, 2007-2010, 2011-2014, 2015-2018); CITR Data 06Jan2017

Triglycerides (mg/dL) — by Age Group; CITR Data 06Jan2017

Triglycerides (mg/dL) — by Era; CITR Data 06Jan2017

Serum creatinine (mg/dL) — by Age Group; CITR Data 06Jan2017

Serum creatinine (mg/dL) — by Era; CITR Data 06Jan2017
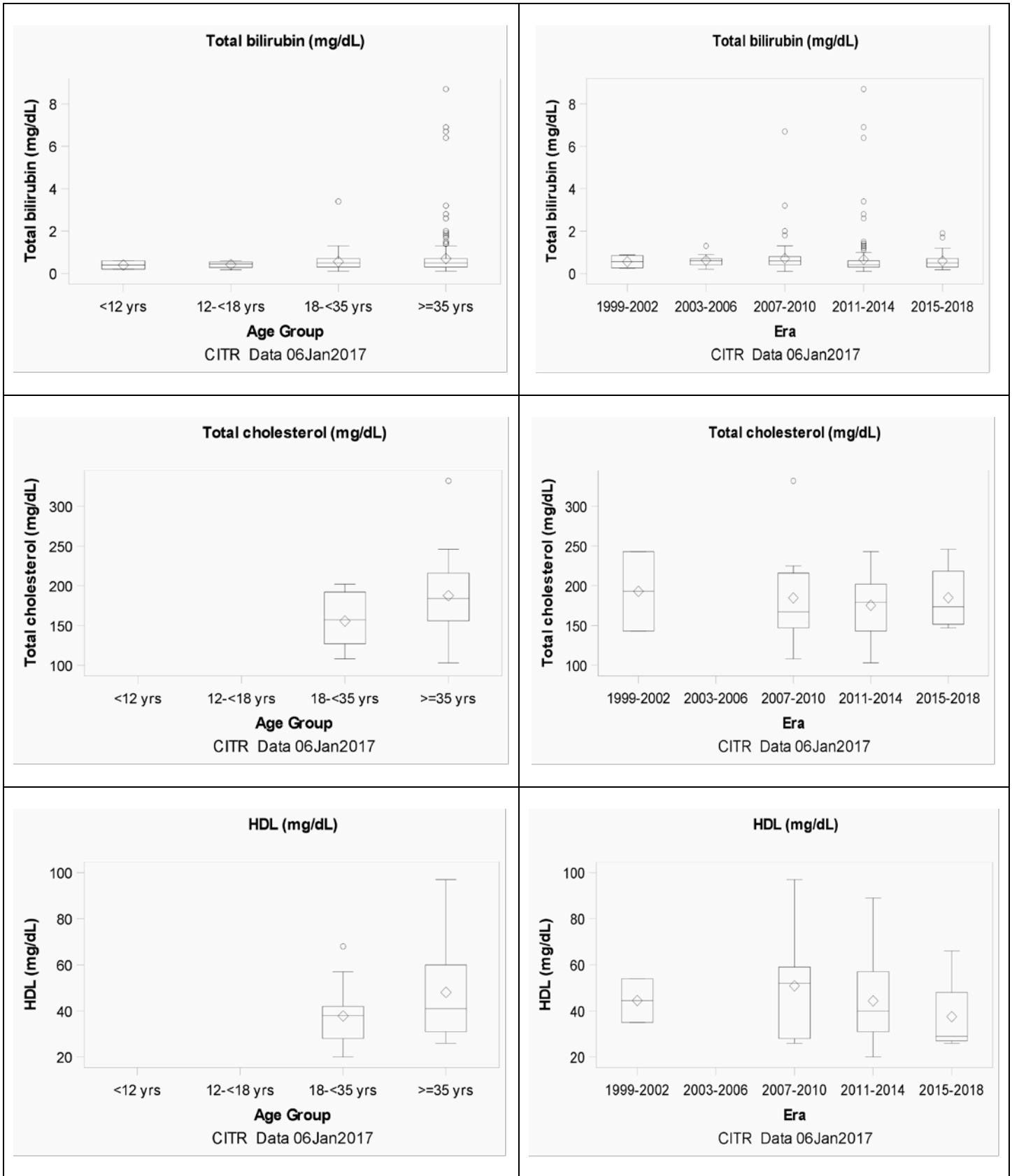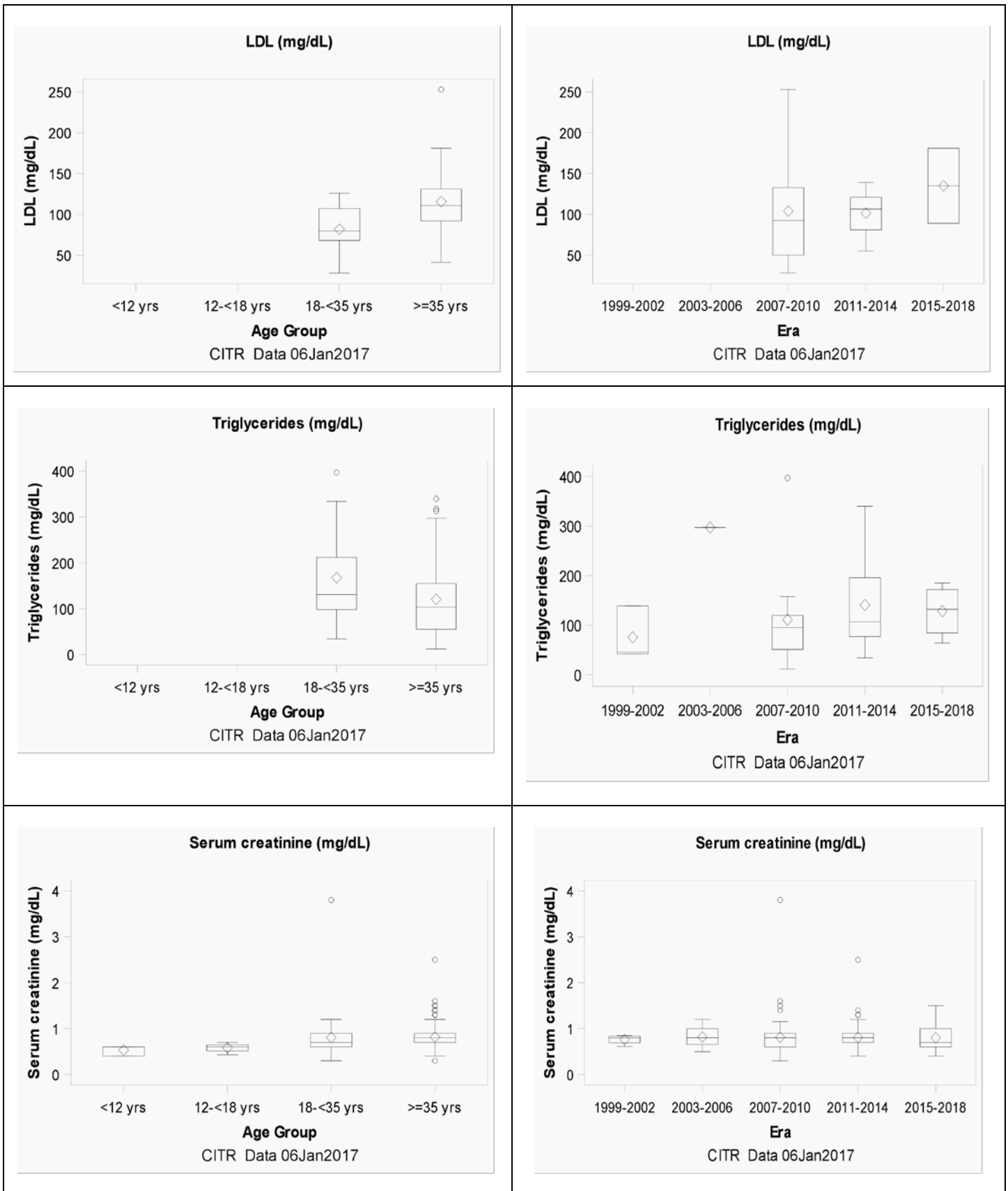
Chapter 3
Islet Processing Characteristics

Table of Contents

Introduction

Many data elements in this Chapter are too sparsely reported to allow any meaningful tabulation of results.   These are indicated as intentionally omitted.

Cold ischemia time is generally quite short, averaging 0.6±0.1 to 2.9±2.4 hours over the eras (Exhibit 3-2).

Although total islet particle count varies significantly by age, significantly increasing with age, total IEQs and IEQs/kg do not (Exhibit 3-3).   The only other islet characteristic that varies by age is endotoxin, with a significant downward trend with increasing age (Exhibit 3.3).   When available, islet viability is at least 90%

The only remarkable correlations between recipient/donor characteristics and islet product characteristics are (Exhibit 3-4):
- Negative correlation between recipient/donor age and total particle count
- Positive correlation between recipient/donor BMI and total IEQs
- Negative correlation between cold ischemia time and both total particle count and total IEQs

Exhibit 3-1
Islet Processing Summary

Data on procurement team and islet processing center relatedness to the transplant center, islet culturing, gradient type, preservation solution, islet purification, density gradient, and microbiology testing are too sparsely reported to allow any meaningful results tabulation. Exhibit 3-1 is intentionally omitted.

Exhibit 3-2
Cold ischemia information

	Era															p
	1999-2002			2003-2006			2007-2010			2011-2014			2015-2018			
	N	Mean	SD	N	Mean	SD	N	Mean	SD	N	Mean	SD	N	Mean	SD	
Time from admission to pancreatectomy (hrs)	4	51.3	19.7	5	40.2	30.0	8	30.6	35.5	33	6.6	6.9	8	8.6	6.8	***
Time from pancreatectomy to transplant (hrs)	0	-	-	8	1.0	0.7	13	4.9	7.8	35	3.9	2.8	8	4.4	1.1	
Time from cross clamp to pancreas recovery (hrs)	0	-	-	0	-	-	0	-	-	0	-	-	0	-	-	
Duration of cold ischemia (hrs)	4	0.6	0.1	9	1.4	0.5	35	2.3	2.1	113	1.8	2.0	19	2.9	2.4	
Culture time (hrs)	0	-	-	0	-	-	0	-	-	0	-	-	0	-	-	

Exhibit 3-3
Islet Product Characteristics (Cumulative through all infusions per recipient)

Infusions	Age Group												p
	<12 yrs			12-<18 yrs			18-<35 yrs			>=35 yrs			
	N	Mean	SE	N	Mean	SE	N	Mean	SE	N	Mean	SE	
Total cell volume	4	4.8	2.2	17	6.8	1.5	76	8.9	0.7	158	9.6	0.5	
Total islet particles (final preparation, 1000s	8	268.3	49.9	23	274.2	34.3	145	308.9	16.4	316	252.2	9.3	**
Embedded islets (%)	0	-	-	1	5.0	-	23	30.5	5.1	80	27.4	2.4	
Islet equivalents (1000s)	9	196.2	40.0	21	201.9	32.7	141	283.5	15.8	306	256.7	10.9	
Islet equivalents(1000s)/kg recipient	3	7.0	0.7	2	3.0	1.9	50	4.3	0.4	136	4.1	0.3	
Total Endotoxin units	3	135.3	48.6	2	185.7	174.3	33	67.4	16.7	89	55.0	5.9	*
Endotoxin units/kg recipient weight	3	3.7	1.7	2	3.6	3.2	32	0.9	0.2	82	0.8	0.1	***
Islet viability	3	90.0	2.9	4	95.8	0.9	47	94.0	0.8	150	93.8	0.4	
Purity	3	5.0	0.6	1	8.0	-	28	27.6	4.7	78	30.3	3.0	

Exhibit 3-4
Correlation of Islet Characteristics with Recipient, Recovery, and Processing Characteristics

Spearman Correlation Coefficients Prob > |r| under H0: Rho=0 Number of Observations											
	Packed cell volume	Total particle count	Trapped islets	Total IEQs infused	IEQs/kg donor	Total beta cells	Beta cells/kg donor	Insulin content	Total endotoxin	Endotoxin/kg donor	Stimulation index
Mean recipient age (yrs)	0.05430 0.3870 256	-0.13269 0.0031 494	-0.11533 0.2437 104	-0.04343 0.3428 479	-0.15288 0.2744 53	. . 0	. . 0	. . 0	-0.03617 0.6864 127	-0.08101 0.3811 119	. . 0
Recipient Weight (kg)	-0.07443 0.5589 64	0.06849 0.3304 204	-0.03611 0.7255 97	0.22336 0.0020 189	-0.13991 0.3177 53	. . 0	. . 0	. . 0	0.17673 0.0545 119	-0.00806 0.9307 119	. . 0
Recipient height	-0.14535 0.2518 64	-0.06347 0.3756 197	-0.08042 0.4312 98	-0.02241 0.7596 189	-0.21214 0.1477 48	. . 0	. . 0	. . 0	0.03423 0.7129 118	-0.06618 0.4861 113	. . 0
Recipient Body Mass Index (kg/m2)	-0.10532 0.4232 60	0.10935 0.1342 189	-0.01489 0.8873 93	0.26385 0.0003 181	-0.11377 0.4413 48	. . 0	. . 0	. . 0	0.19246 0.0411 113	0.04363 0.6463 113	. . 0
Hours from admission to pancreatectomy	0.02055 0.9258 23	-0.11576 0.4654 42	-0.40272 0.0783 20	-0.23492 0.1557 38	-0.06498 0.7796 21	. . 0	. . 0	. . 0	-0.09516 0.6509 25	-0.15667 0.4862 22	. . 0
Hours from pancreatectomy to transplant	-0.20781 0.2705 30	-0.10535 0.4761 48	0.34642 0.0973 24	0.12137 0.4326 44	0.05347 0.7911 27	. . 0	. . 0	. . 0	-0.34306 0.0588 31	-0.26637 0.1706 28	. . 0
Cold ischemic time (hrs)	0.21030 0.2253 35	-0.24890 0.0015 160	-0.15046 0.1569 90	-0.30675 0.0002 145	-0.06474 0.7435 28	. . 0	. . 0	. . 0	0.10344 0.2822 110	0.19443 0.0491 103	. . 0

Chapter 4
Autologous Islet Recipient Medications

This Chapter is intentionally left blank

Chapter 5
Graft Function

Table of Contents

Introduction

Unlike with allo-islet transplantation, time to first insulin independence is not a measure of engraftment for auto-islet transplantation. Exhibit 5-1 is left blank intentionally.

Achievement and durability of the primary outcomes are best exhibited as prevalence rates post initial transplant (very few auto-ITX recipients received a second transplant), and these are influenced by various patient and management factors.   First, there were no significant differences in durability of **insulin independence** following Auto-ITx across the age groups (Exhibit 5-2A). All other factors were investigated by age group.

Recipients ≥35 years old (Exhibit 5-2B)

Insulin independence rates (Exhibit 5-2B) decline steadily over the 5 years post auto-ITx transplant, with very few retaining insulin independence at 5 years.

There were very few recipients with data reported on baseline hypoglycemia status; these results are not displayed. Hypoglycemia is not commonly assessed at baseline in Auto-Itx, as recipients are most often non-diabetic and not treated with insulin prior to surgery.

Baseline HDL>50 U/L showed greatly improved rates of insulin independence (Exhibit 5-2B/A, p=0.0044), as did triglycerides<65 (Exhibit 5-2B/B, p=0.0022).

Absence of diagnostic ERCP improved insulin independence rates (Exhibit 5-2B/C, p-0.0035), as did absence of treatment ERCP (Exhibit 5-2B/D, p=0.0055).

Chronic pancreatitis as the indication for auto-ITx reduced insulin independence rates (Exhibit 5-2B/E, p=0.0035).

Recipients 18-35 years old

Greater than 750K particles at islet count is associated with 100% insulin independence retention (Exhibit 5-2C/A, p<0.0001), and ≥275K IEQs showed much higher rates of insulin independence retention (Exhibit 5-2C/B, p=0.0049), with about 70% retaining insulin independence throughout the 5 years of follow-up.

Absence of diagnostic ERCP also exhibited greater insulin independence levels (Exh 5-2C/D, p=0.0085) in this age group.

Recipients <18 years old

These groups had too small sample size to uncover any factors associated with improved levels of insulin independence following transplantation (Exhibits 5-2C and 5-2D).

Age was not a significant factor **of C-peptide≥0.3 ng/mL** prevalence over five years post auto-ITx (Exhibit 5-4A). For the ≥35-year-old patients, largely the same variables that influenced insulin independence rates also influenced rates of C-peptide≥0.3 mg/dL (Exhibit 5-4B). Lower HbA1c at baseline, higher particles at count, >300K IEQs infused, no prior treatment ERCP, no prior plastic stent, no prior other medical procedure, indication other than chronic pancreatitis, partial pancreatectomy all exhibited improved retention of C-peptide>-0.3ng/mL over 5 years. The differences by era are not readily explained.

In the 18-35 year-old's, higher number of islet particles at count, and IEQs infused improved rates of C-peptide≥0.3ng/mL (Exhibit 5-4C). Observed differences across eras are not clearly explainable. There were no detectable factors for C-peptide≥0.3 ng/mL in the younger age groups.

Almost all patients had **fasting blood glucose (FBG) of 60-140 mg/dL** at baseline, and the prevalence rates remained at very high levels (>95%) through five years post-transplant, across all the age groups except ≥35 years old, in which there was a steady decline of FBG 60-140 each year post transplant, down to about 50% at 5-years (Exhibit 5-5A, p=0.0006) In this age group, fasting C-peptide>=0.3 ng/mL, and partial pancreatectomy, showed remarkably higher rates of FBG 460-140 (Exhibit 5-5B/D, p<0.0001).

No specific factors were associated with FBG 60-140 in auto-ITx recipients in age groups 18-<35, 12-<18, and <12 (Exhibit 5-5C, 5-5D, 5-5E).

All auto-ITx patients had **HbA1c<7.0%** at baseline. These rates remained very high (>95%) for young children and those aged 18-35, but declined to about 60% at 5-years post-transplant in 12-18-year-olds and adults ≥35 (Exhibit 5-6A). There were no specific factors influencing HbA1c<7.0% in the other age groups.

Severe hypoglycemic events (requiring the assistance of another person; SHE) were virtually non-existent at baseline and remained so throughout 5-years follow-up post auto-islet in all age groups (Exhibit 5-7).

Insulin dose (Exh 5-9) did not vary by age, era, total IEQs infused, or pancreatitis etiology. Although there is much missing data in this outcome, it is considered missing at random, i.e., not based on whether there was or was not insulin independence.

Fasting C-peptide boxplots (Exhibit 5-10) did not vary over time by age group, though they varied substantially by era differences may be due to age differences across eras.

HbA1c boxplots (Exhibit 5-11) varied by era, age group, total IEQs (higher IEQs were better), and pancreatitis etiology.

Fasting blood sugar as a continuous variable varied substantially by age with worse outcomes in those aged ≥35, was improved with ≥325K total IEQs infused, and varied by pancreatitis etiology.

For most of the primary metabolic endpoints, data interpretation is limited by the ~50% levels of missing data, for much follow-up including insulin independence and insulin use. All indications are that the data are missing at random, i.e., not selectively for insulin use or independence. From available data, **Insulin Dose** (Exh 5-9) when reported did not vary by age, era, total IEQs infused, or pancreatitis etiology. **Fasting C-peptide** boxplots (Exhibit 5-10) decreased over time after TPIAT and differed by era and pancreatitis etiology. **HbA1c boxplots** (Exhibit 5-11) varied by era, age group, total IEQs (higher IEQs were better), and pancreatitis etiology. **Fasting plasma glucose (FPG)** as a continuous variable varied substantially by age, total IEQs infused (≥325K were better), and varied by pancreatitis etiology.   HbA1c and FPG were worse in those ≥35 years of age, as was HbA1c in those 12 - <18 years of age. HbA1c and FPG patterns differed by etiology of disease, which appears in part driven by worse glycemic control in Auto-Itx for alcoholic pancreatitis. Alcoholic pancreatitis has previously been associated in the literature with lower islet mass isolated for transplant and lower rates of insulin independence.

Exhibit 5-1A
First Achievement of Insulin Independence
This exhibit is intentionally omitted

Exhibit 5-2A
Prevalence of Insulin Independence Post Last Infusion by Age Group (p=NS)

| Children 12 and under	Adolescents 12 to 18

Adults 18 to 35	Adults 35 and over
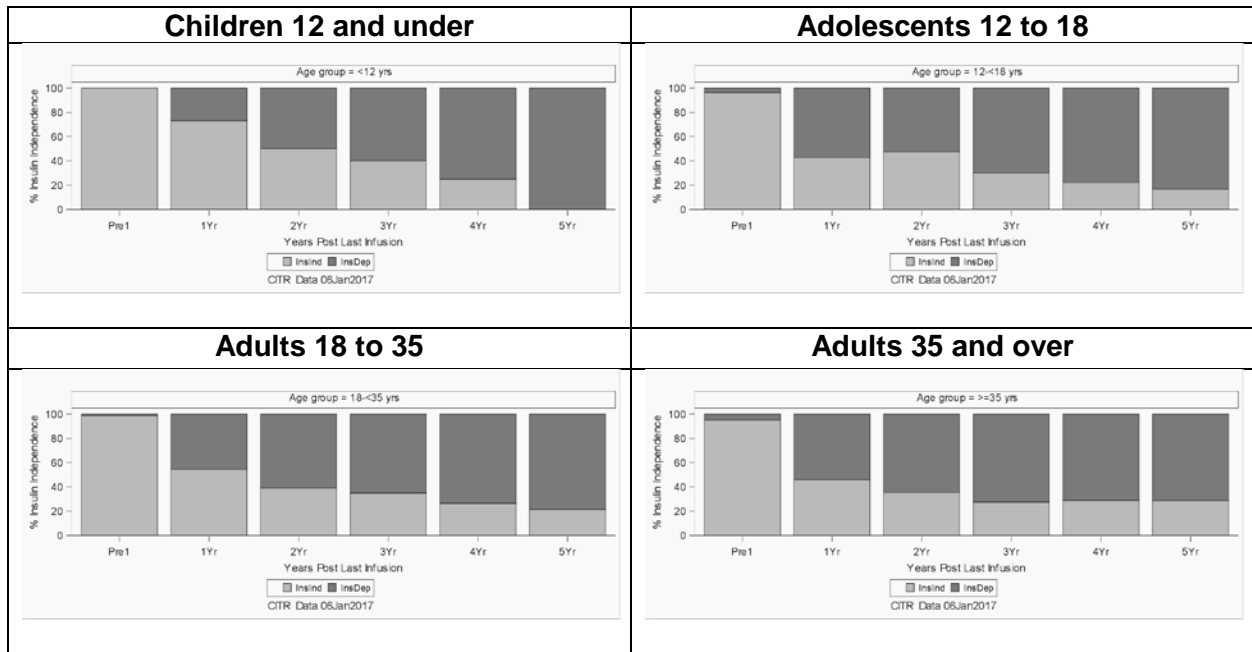
Exhibit 5-2B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Insulin Independence
Post Last Infusion among Recipients 35 and over

A. Baseline HDL (p=0.0044)

B. Baseline triglycerides (p=0.0022)

C. Diagnostic ERCP (p=0.0035)

D. Treatment ERCP (p=0.0055)

E. Indication: Chronic pancreatitis (p=0.0035)
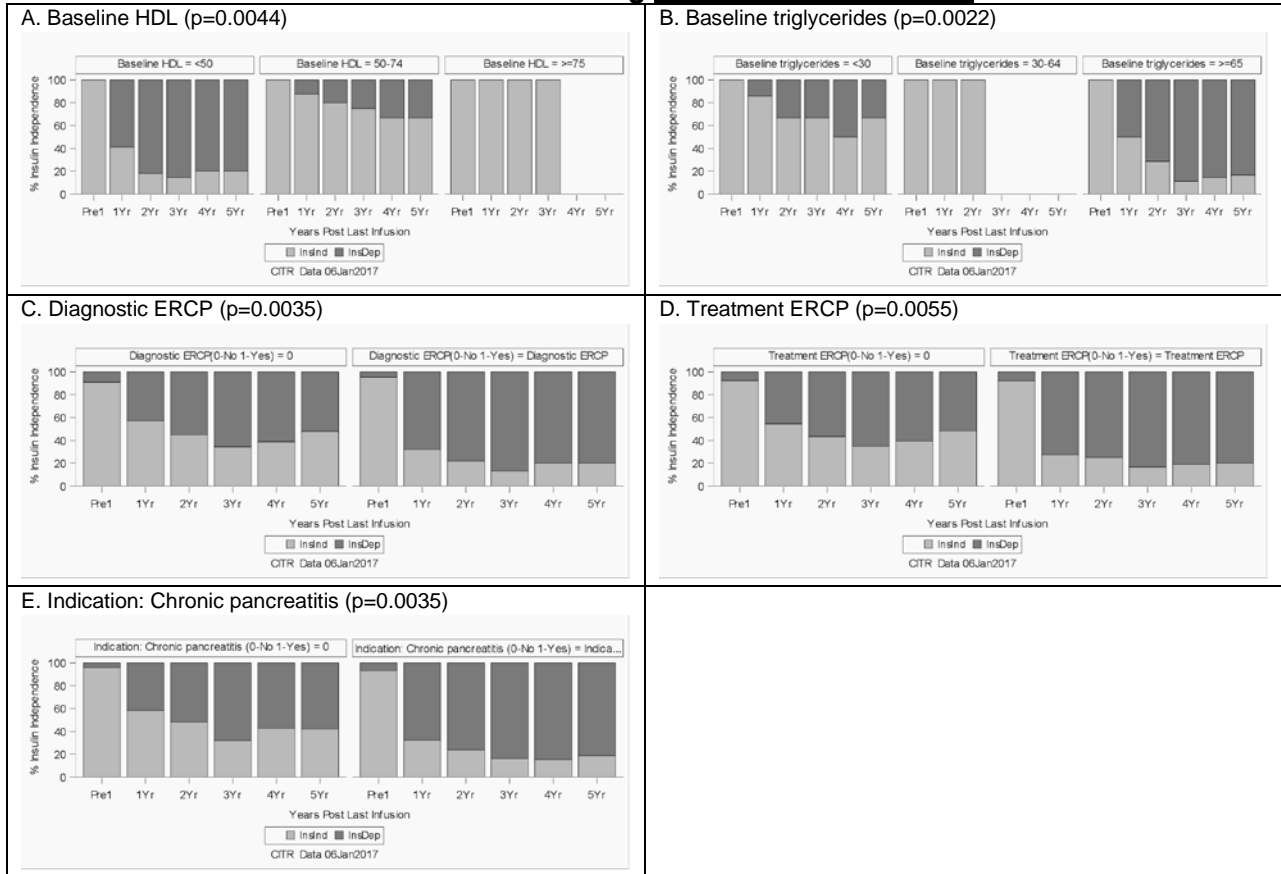
Exhibit 5-2C
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Insulin Independence
Post Last Infusion among <u>Recipients 18 to 35</u>
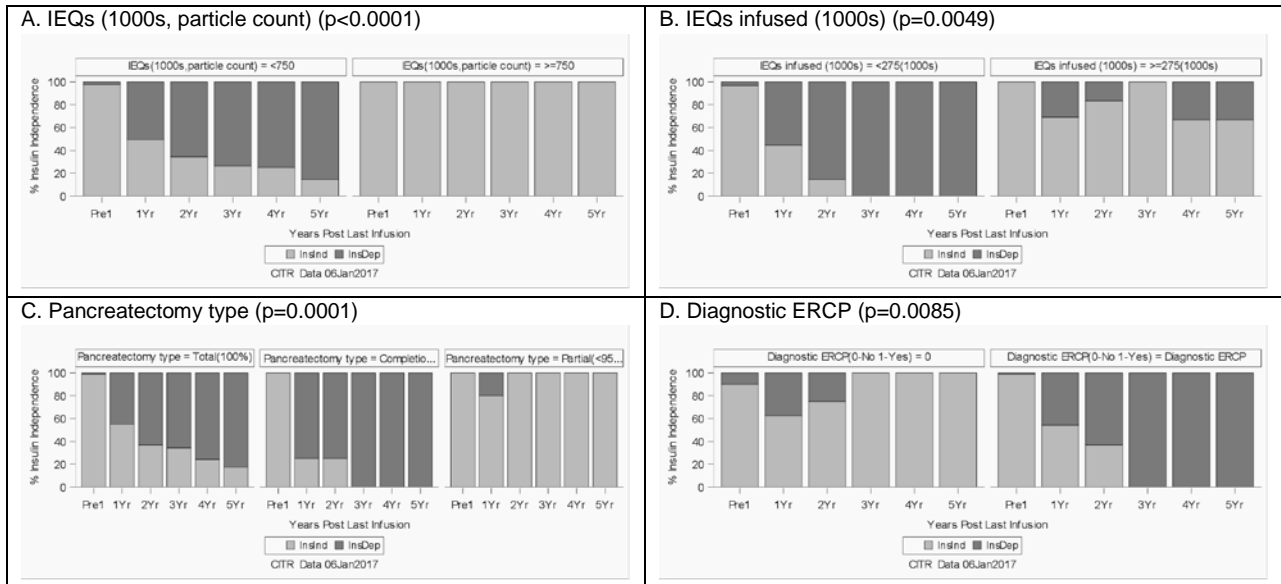
Exhibit 5-2D
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Insulin Independence
Post Last Infusion among <u>Recipients 12 to 18</u>

None

Exhibit 5-2E
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Insulin Independence
Post Last Infusion among <u>Recipients 12 and under</u>

None

Exhibit 5-3
Retention of C-peptide ≥0.3 ng/mL Post Last Infusion

Exhibit is intentionally omitted

Exhibit 5-4A
Prevalence of C-peptide ≥0.3 ng/mL Post Last Infusion by Age Group (p=NS)
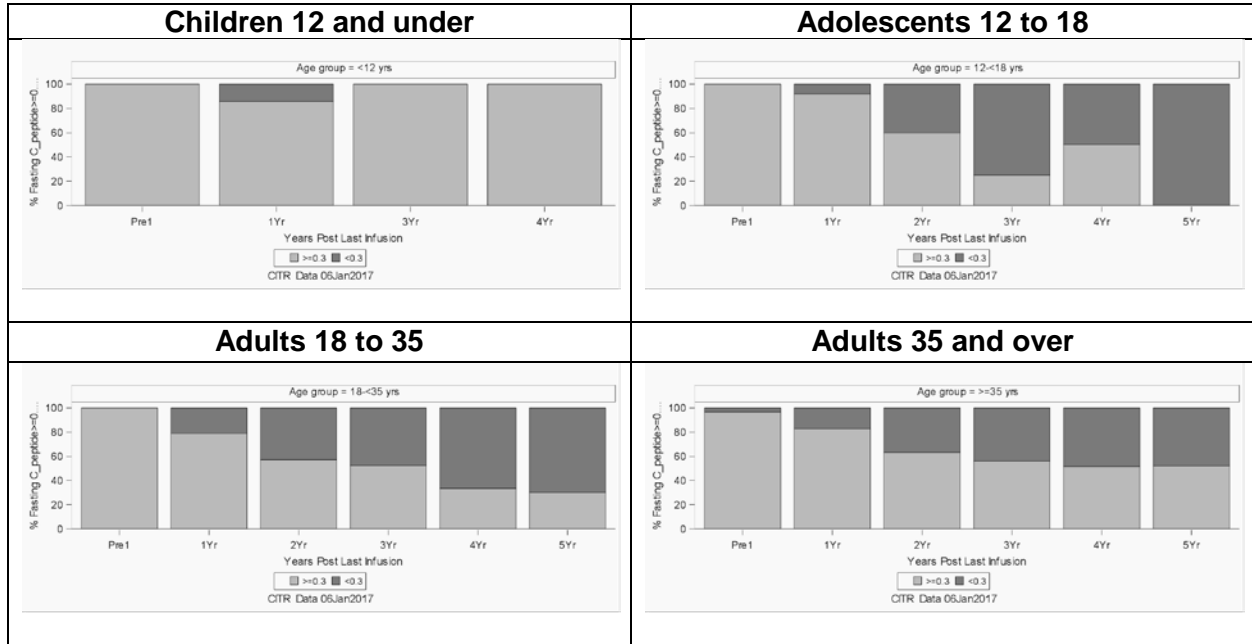
Exhibit 5-4B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of C-peptide ≥0.3 ng/mL
Post Last Infusion among <u>Recipients 35 and over</u>
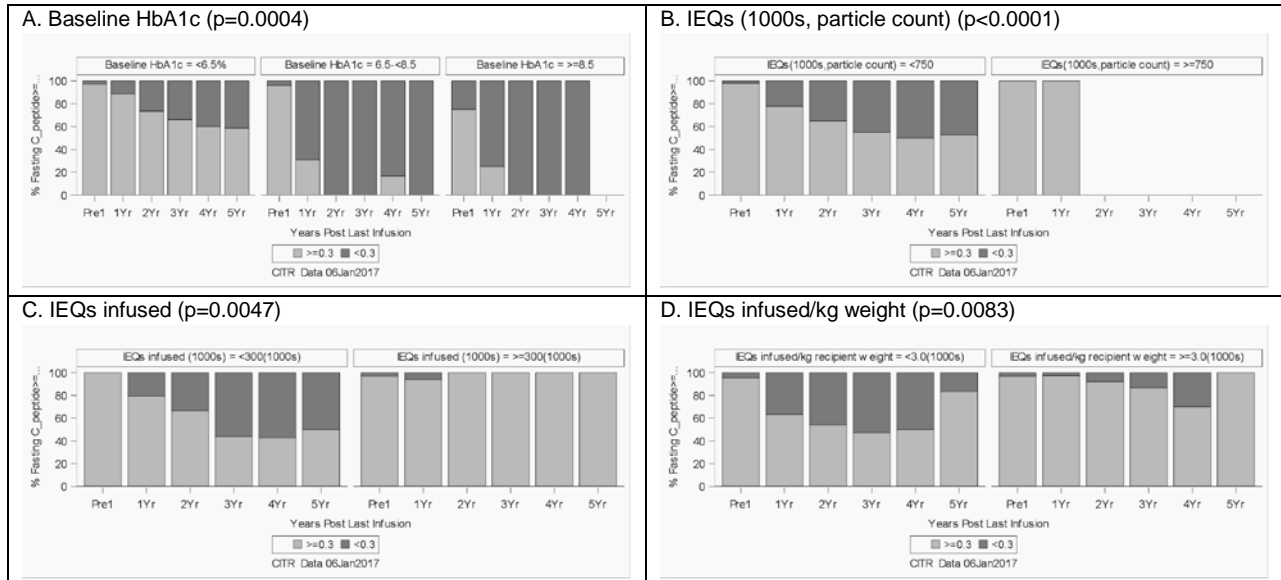
Exhibit 5-4B (continued)
Univariate Effects of Individual Variables (p<0.01) on Prevalence of C-peptide ≥0.3 ng/mL
Post Last Infusion among <u>Recipients 35 and over</u>

E. Treatment ERCP (p=0.0050)

F. Plastic Stent (p=0.01)

G. Other prior medical procedure (p=0.0080)

H. Indication: Chronic pancreatitis (p=0.0050)
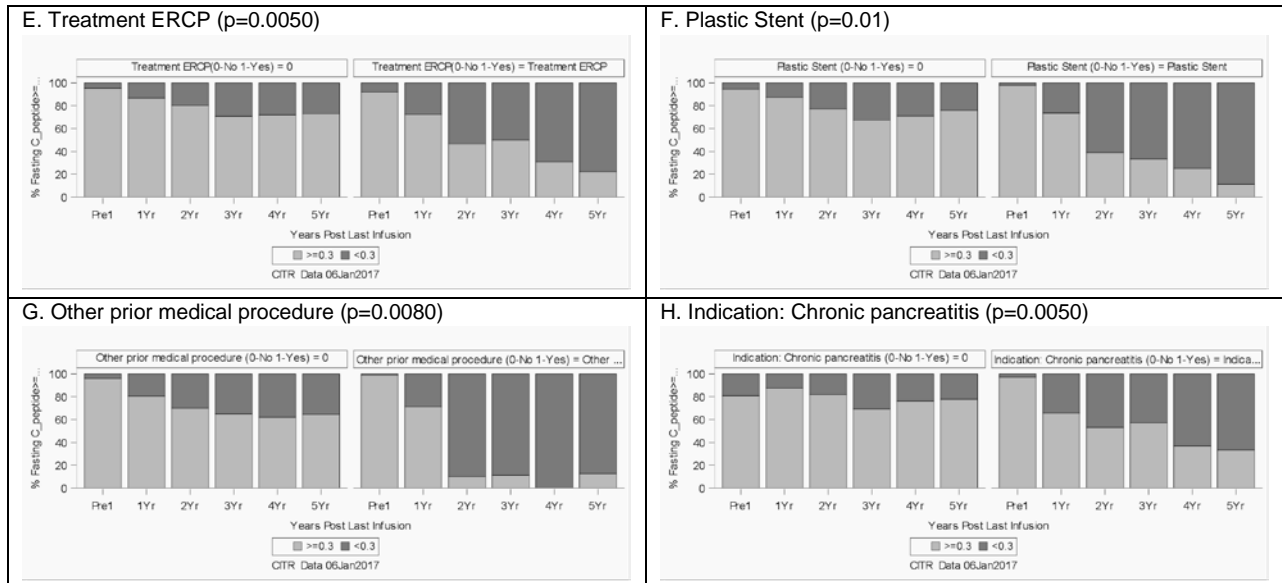
Exhibit 5-4C
Univariate Effects of Individual Variables (p<0.01) on Prevalence of C-peptide ≥0.3 ng/mL
Post Last Infusion among <u>Recipients 18 to 35</u>

A. Islet particles (1000s) (p=0.0015)

B. IEQs (1000s, particle count) (p=0.0003)

C. Diagnostic ERCP (p=0.0033)
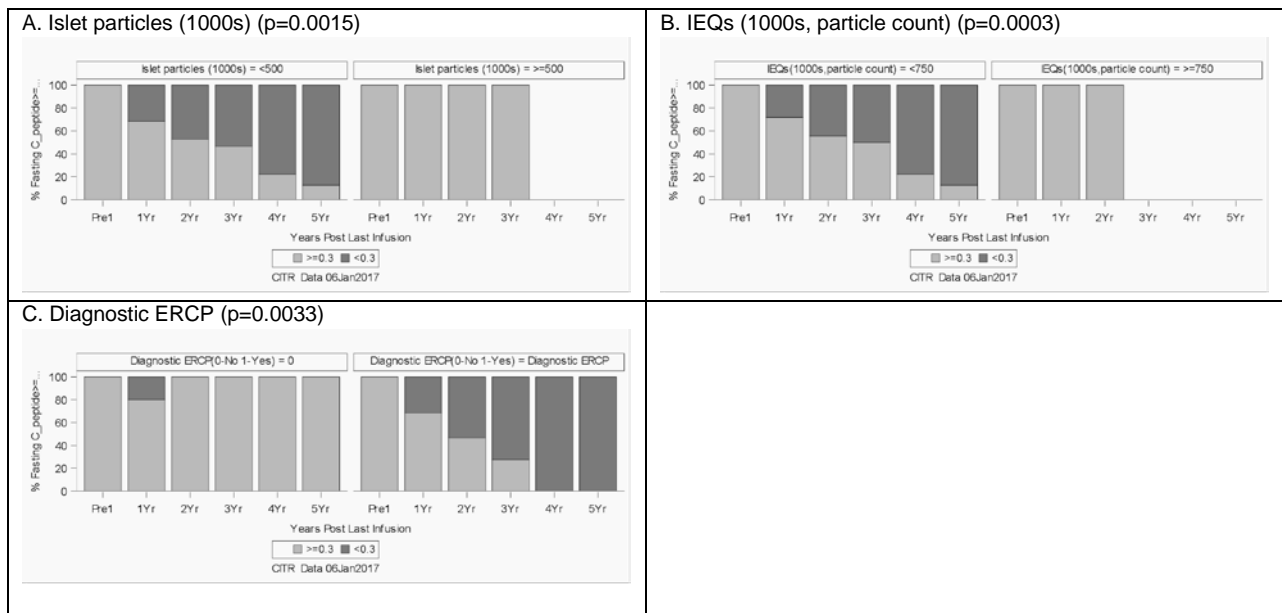
Exhibit 5-4C(continued)
Univariate Effects of Individual Variables (p<0.01) on Prevalence of C-peptide ≥0.3 ng/mL
Post Last Infusion among <u>Recipients 18 to 35</u>

D. Era (p=0.0007)
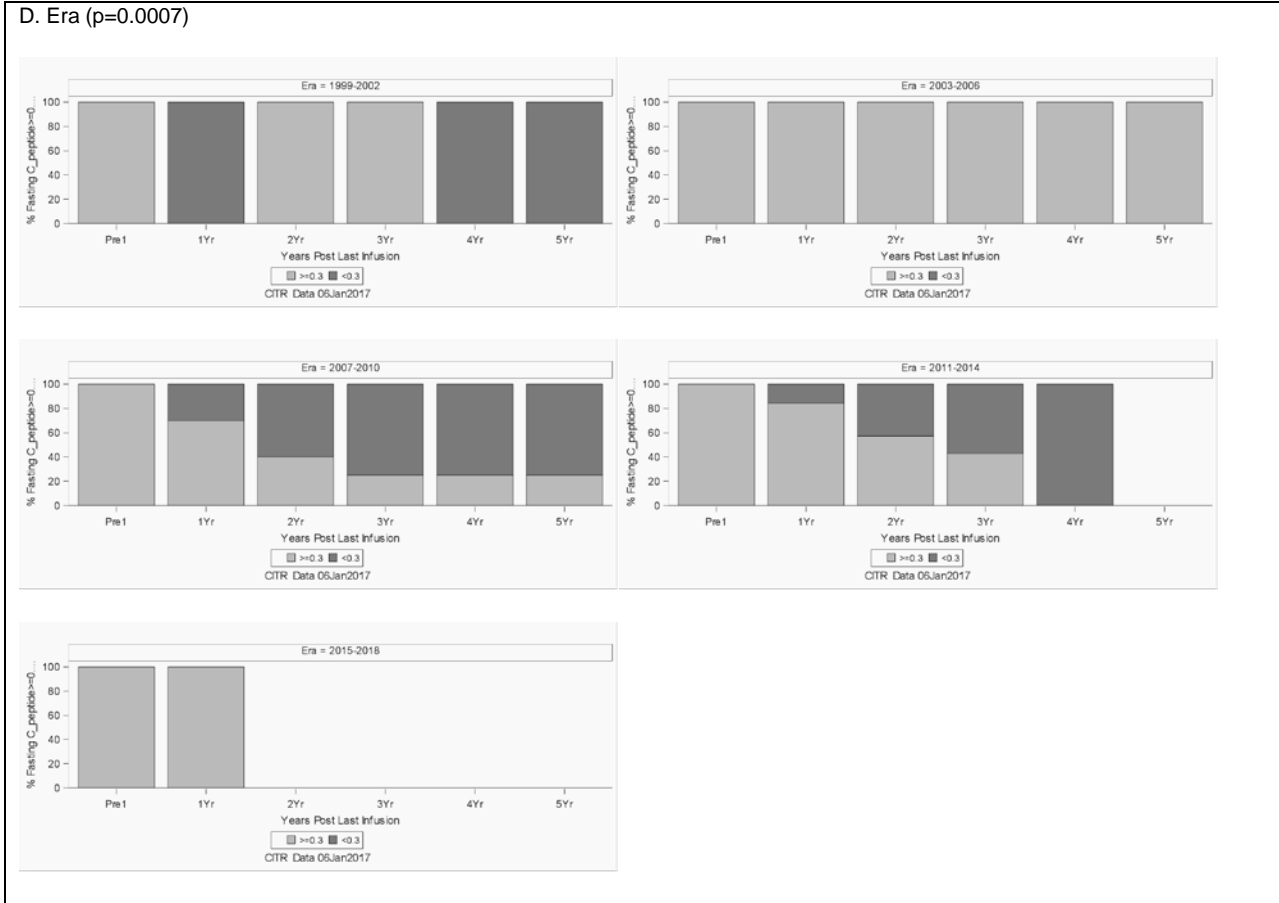
Exhibit 5-4D
Univariate Effects of Individual Variables (p<0.01) on Prevalence of C-peptide ≥0.3 ng/mL
Post Last Infusion among <u>Recipients 12 to 18</u>

None

Exhibit 5-4E
Univariate Effects of Individual Variables (p<0.01) on Prevalence of C-peptide ≥0.3 ng/mL
Post Last Infusion among <u>Recipients 12 and under</u>

None

Exhibit 5-5A
Prevalence of Fasting Blood Glucose 60-140 mg/mL Post Last Infusion by Age Group
(p=0.0006)

Children 12 and under	Adolescents 12 to 18

Adults 18 to 35	Adults 35 and over
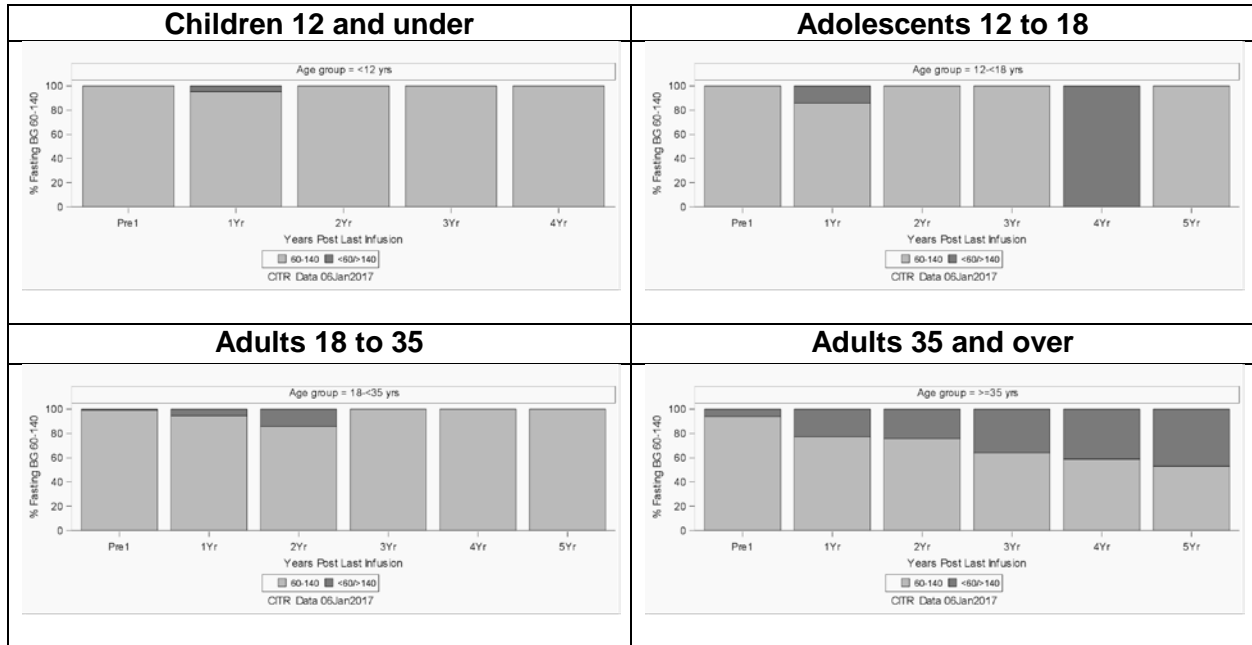
Exhibit 5-5B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Fasting Blood
Glucose 60-140 mg/mL Post Last Infusion among Recipients 35 and over

A. Baseline fasting C-peptide (p<0.0001)	B. Baseline CKD-GFR (p<0.0001)
	D. Pancreatectomy type (p<0.0001)
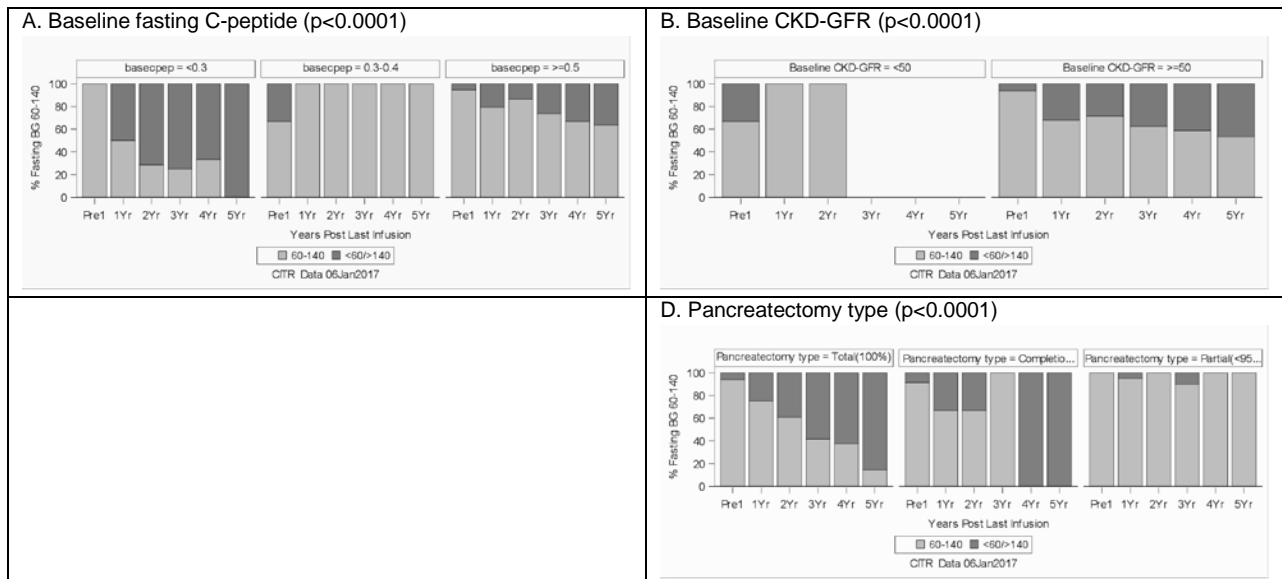
Exhibit 5-5C
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Fasting Blood Glucose 60-140 mg/mL Post Last Infusion among <u>Recipients 18 to 35</u>

None

Exhibit 5-5D
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Fasting Blood Glucose 60-140 mg/mL Post Last Infusion among <u>Recipients 12 to 18</u>

None

Exhibit 5-5E
Univariate Effects of Individual Variables (p<0.01) on Fasting Blood Glucose 60-140 mg/mL Post Last Infusion among <u>Recipients 12 and under</u>

None

Exhibit 5-6A
Prevalence of HbA1c<7.0% Post Last Infusion by Age Group (p<0.0001)

Children 12 and under	Adolescents 12 to 18
Adults 18 to 35	Adults 35 and over
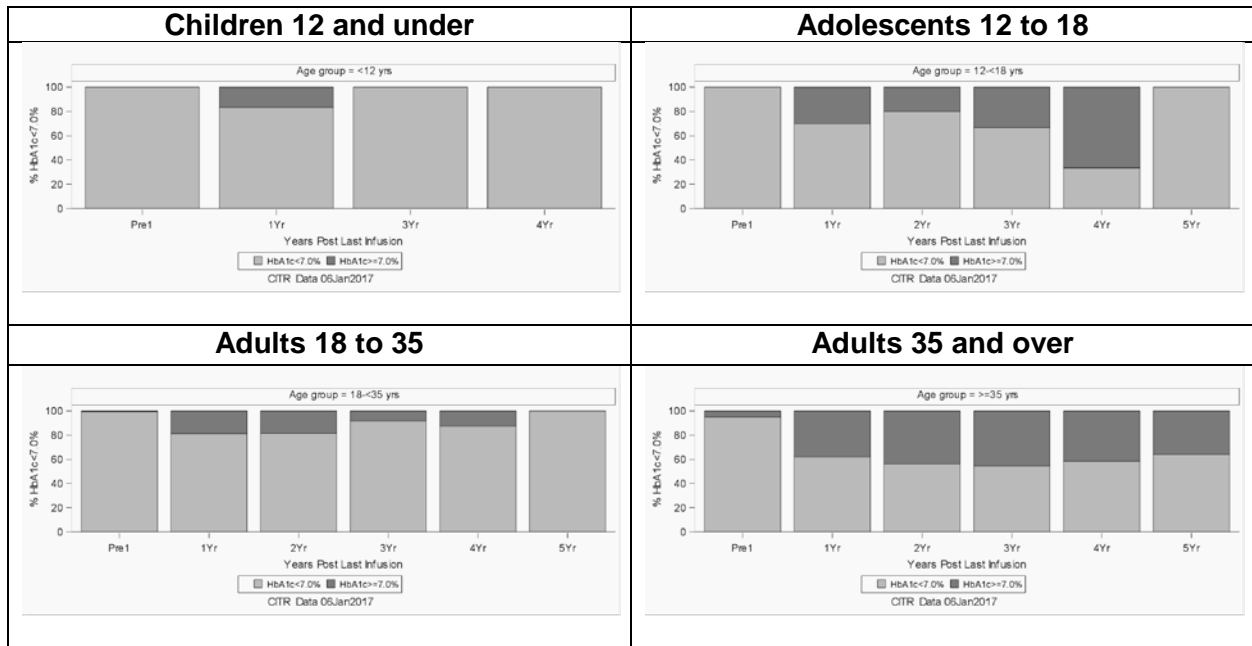
Exhibit 5-6B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of HbA1c<7.0% Post Last Infusion among <u>Recipients 35 and over</u>

C. Indication: Other (p=0.0059)	
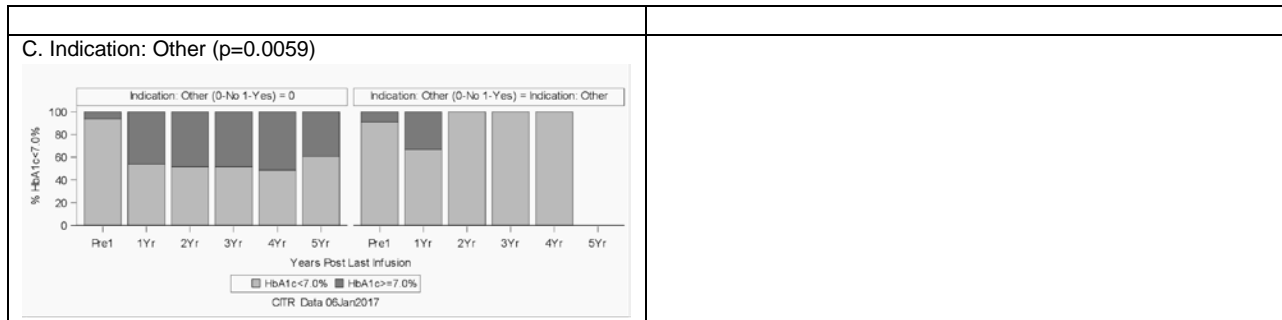
Exhibit 5-6B (continued)
Univariate Effects of Individual Variables (p<0.01) on Prevalence of HbA1c<7.0% Post Last Infusion among <u>Recipients 35 and over</u>

D. Pancreatitis etiology (p<0.0001)
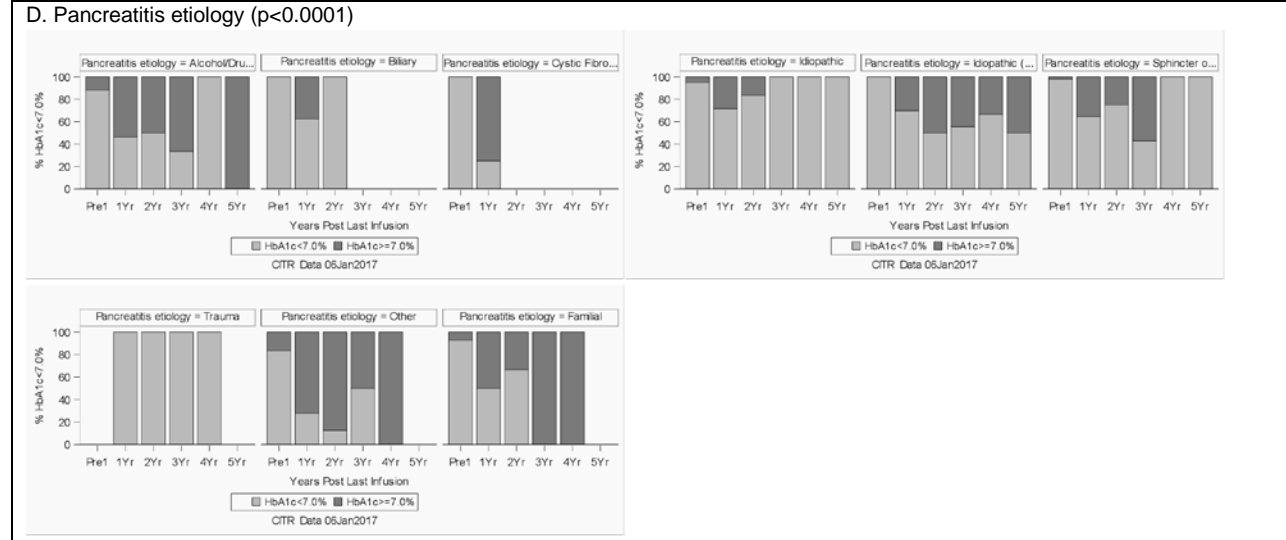
Exhibit 5-6C
Univariate Effects of Individual Variables (p<0.01) on Prevalence of HbA1c<7.0% Post Last Infusion among <u>Recipients 18 to 35</u>

None

Exhibit 5-6D
Univariate Effects of Individual Variables (p<0.01) on Prevalence of HbA1c<7.0% Post Last Infusion among <u>Recipients 12 to 18</u>

None

Exhibit 5-6E
Univariate Effects of Individual Variables (p<0.01) on HbA1c<7.0% Post Last Infusion among <u>Recipients 12 and under</u>

None

Exhibit 5-7
Prevalence of Absence of Severe Hypoglycemic Events Post Last Infusion by Age Group
(p<0.0001)
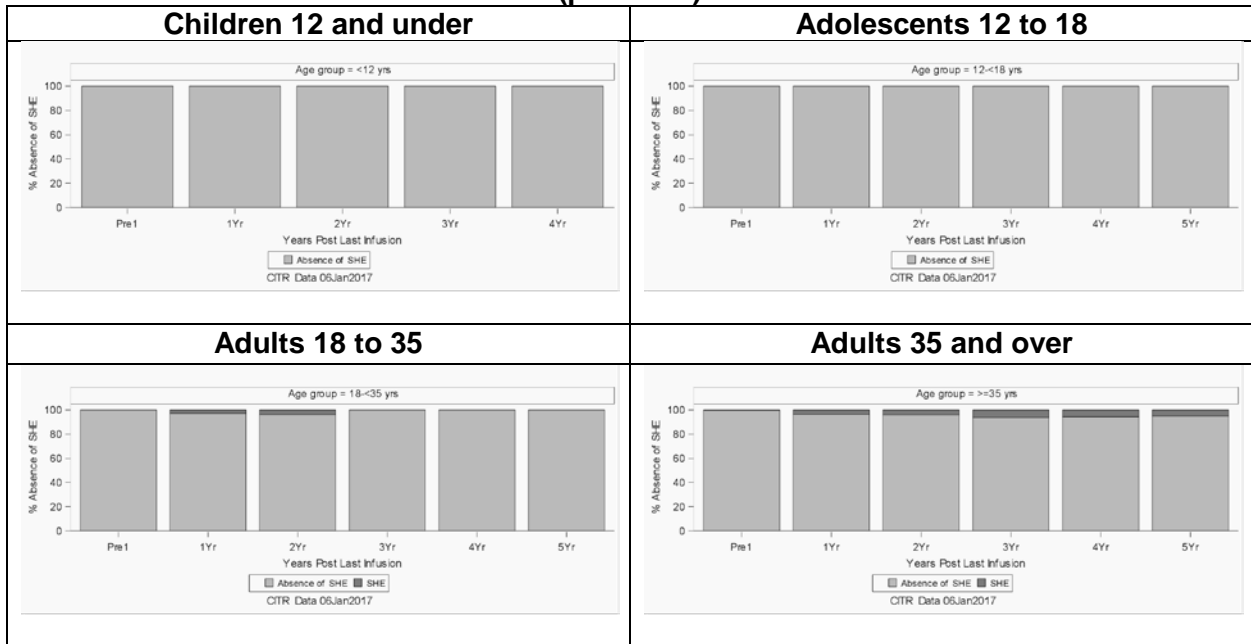
Exhibit 5-8
Intentionally omitted

Exhibit 5-9
Insulin Dose (U/day) Post Last Infusion
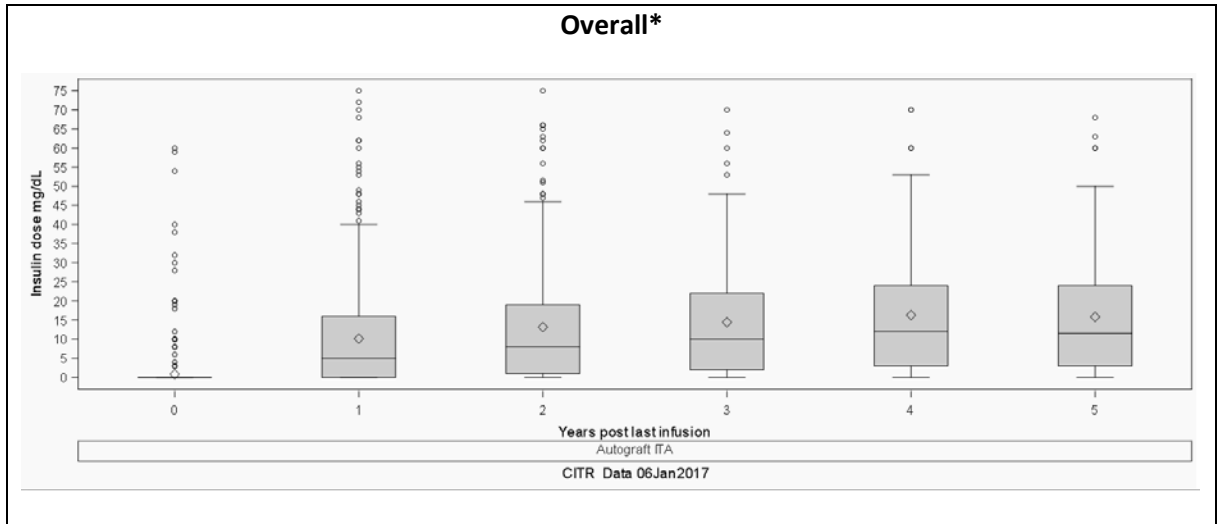
*No factors significant at p<0.01

Exhibit 5-10
Fasting C-peptide (ng/mL) Post Last Infusion
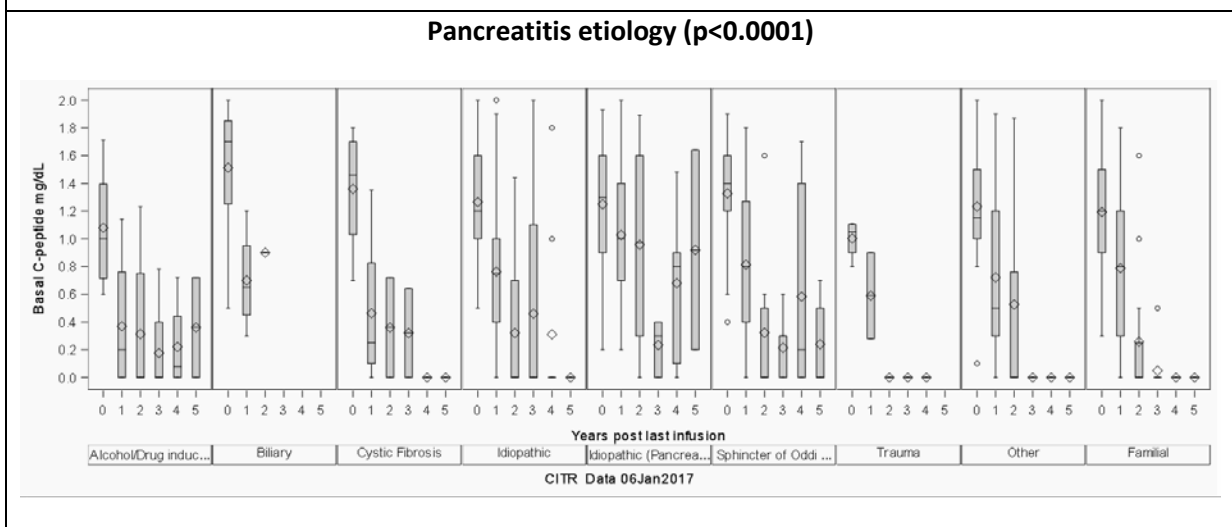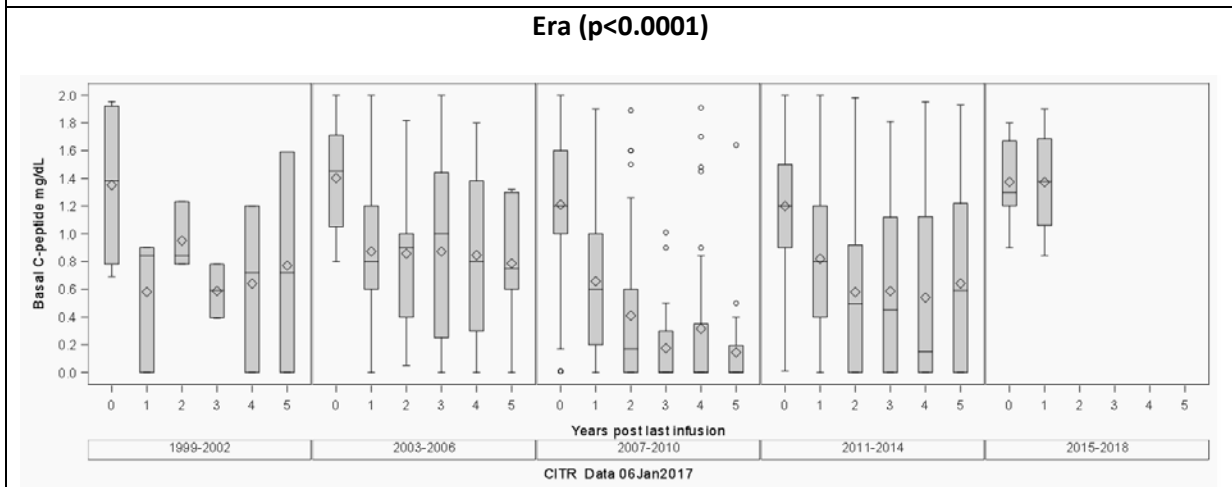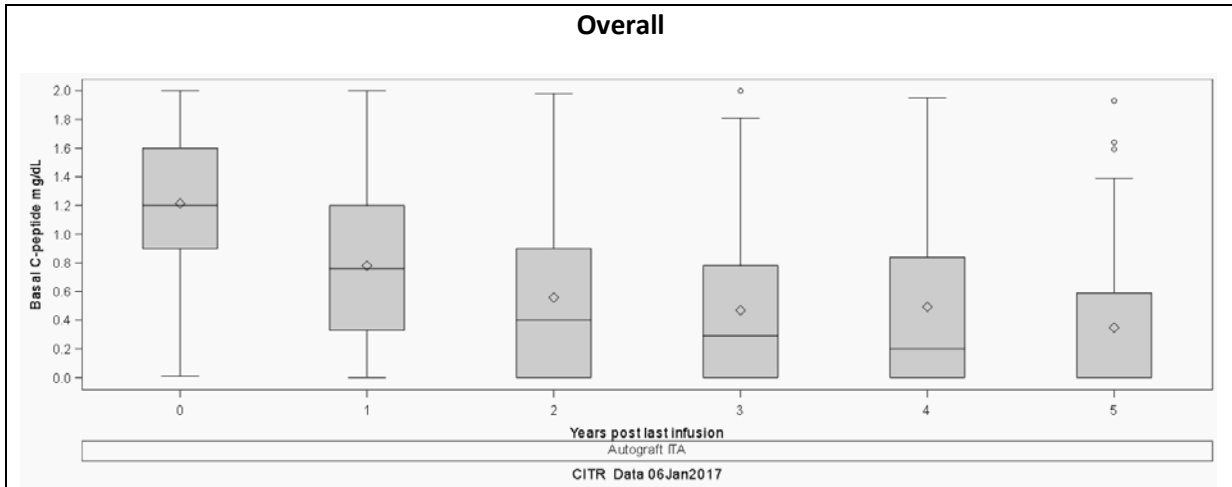
Exhibit 5-11
HbA1c (%) Post Last Infusion

Overall

Age (p<0.0001)

Total IEQs (p=0.0043)
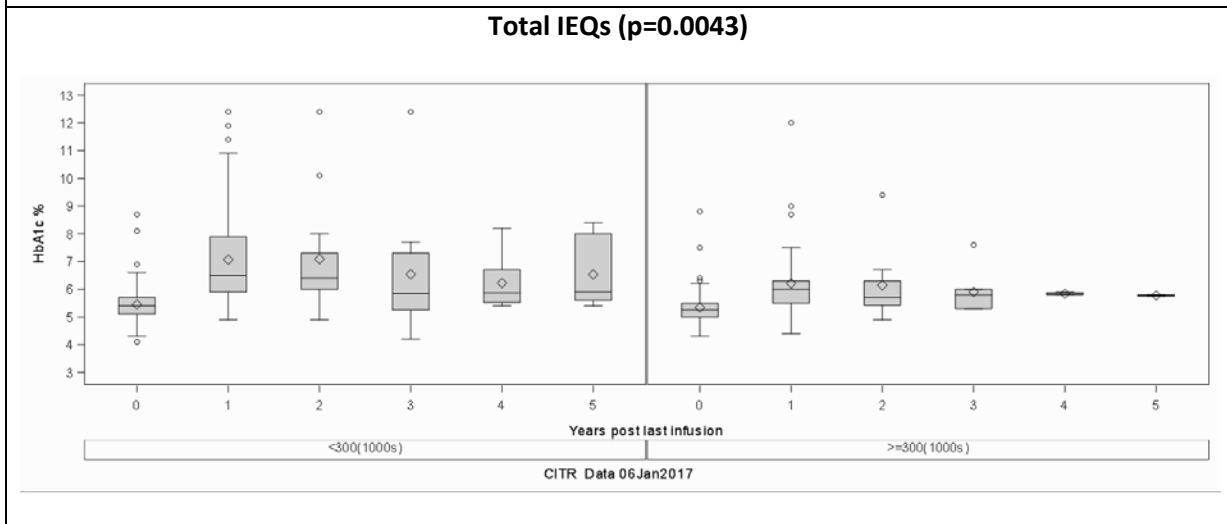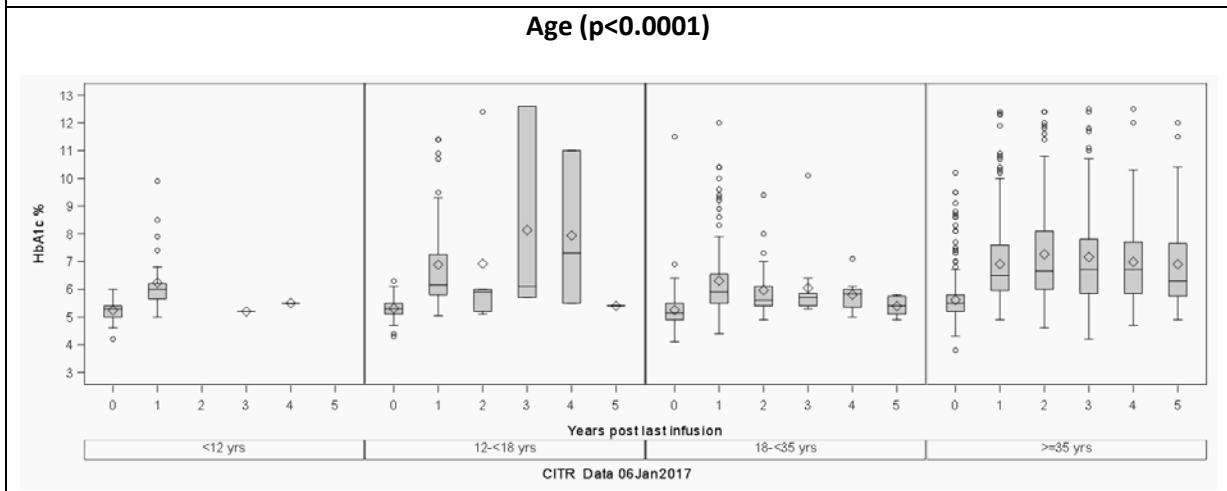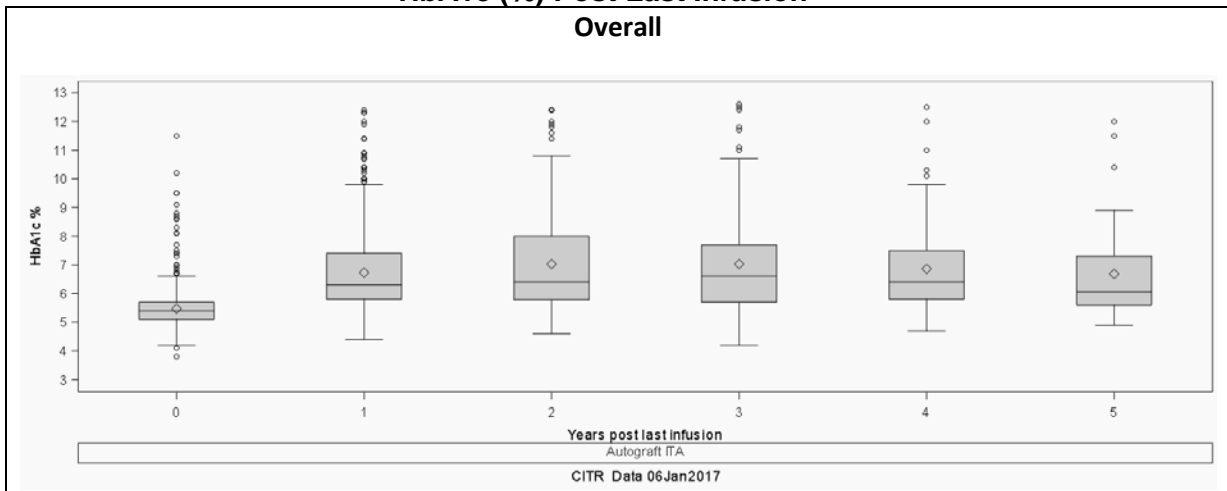
Exhibit 5-11 (continued)
HbA1c (%) Post Last Infusion

Pancreatitis etiology (p<0.0001)
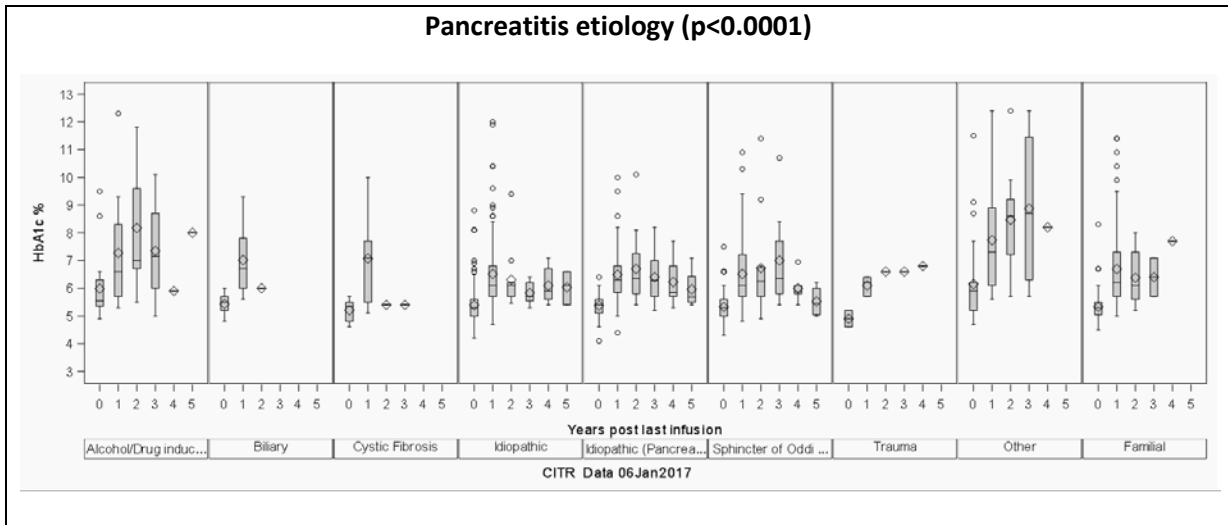
Exhibit 5-12
Fasting Blood Glucose (mg/dL) Post Last Infusion
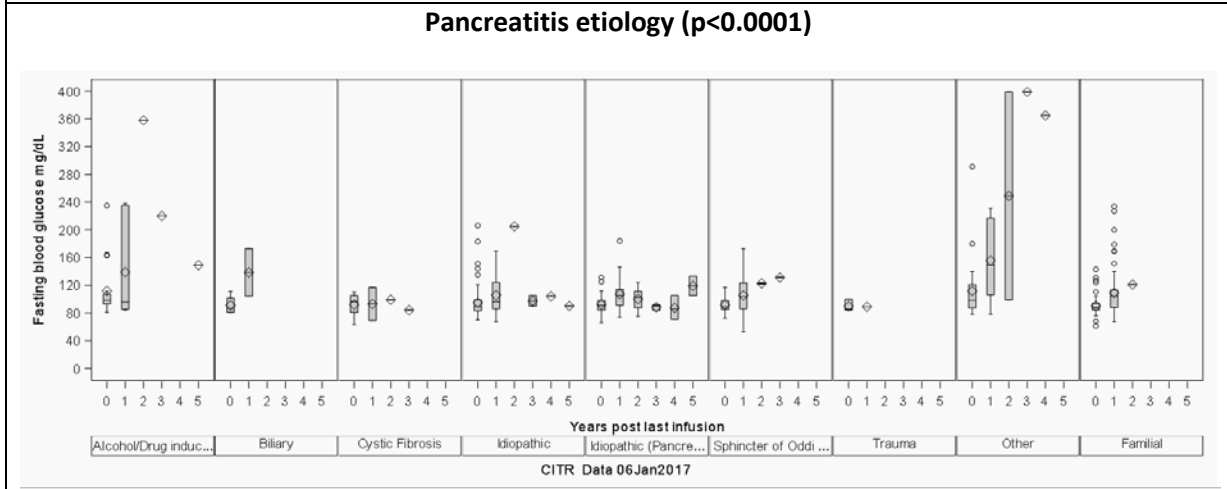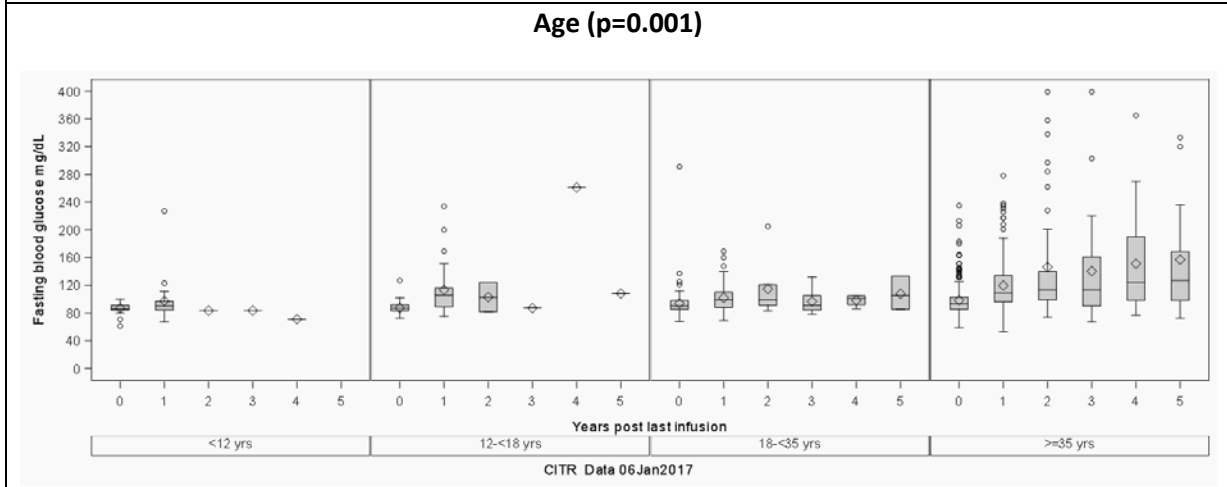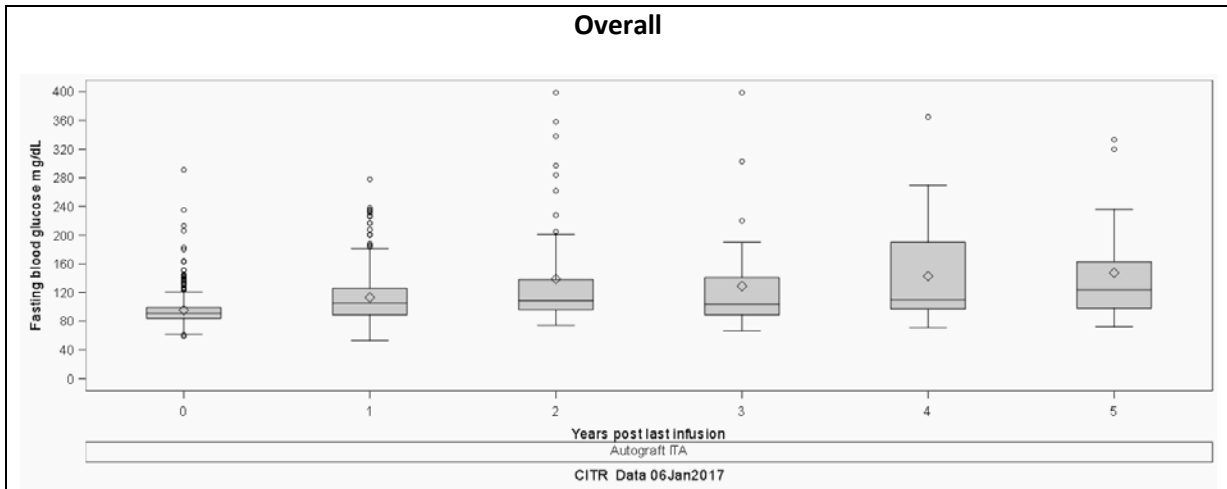
Appendix A: Autologous Islet Transplant Center Contributors

(Centers and Staff are listed in alphabetical order)
(=inactive sites; #=data not included in 1st Annual Autograft Report)*

Baylor Regional Transplant Institute
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Deborah Seale
Cheryl Smyth
Juan Anthony Thompson
Patti Wilson

Appendix A: Autologous Islet Transplant Center Contributors *(continued)*
(Centers and Staff are listed in alphabetical order)
(*=inactive sites; #=data not included in 1st Annual Autograft Report)

University of California, San Francisco
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Peggy Schaeffer
Amit Sharma
Yoshiko Tamura
Caitlin Winkler

Appendix A: Autologous Islet Transplant Center Contributors *(continued)*
(Centers and Staff are listed in alphabetical order)
(*=inactive sites; #=data not included in 1st Annual Autograft Report)

CITR Coordinating Center

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Co-PI: Donald Stablein

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Sara Jolles
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Elizabeth Whitlock
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(Members are listed in alphabetical order)

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Marlon Levy
Bashoo Naziruddin
Hongjun Wang

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Data Elements Committee

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Parastoo Dinyari
Fouad Kandeel
Francois Pattou

Transplant Coordinators/Data Managers Committee

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Nathaniel Brigle
Jill Buss
Coralie Camillo
Lauren Card
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Sallie Carpentier
Kerry Crisalli
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Sandrine Demuylder-Mischler
Parastoo Dinyari
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Anne Farrow
Sheila Fedorek
Natalie Fillman
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Wilma Heemstra
Genevieve Hobbs
Kathy Howe
Erica Hudson
Kristina Johnson
Abdullah Karabala
Veerle Kemels
Matthew Kime
Michael Knoll
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Ursule Van de Velde
Evelien van Rossenberg