Third Autograft Report

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Sponsored by:
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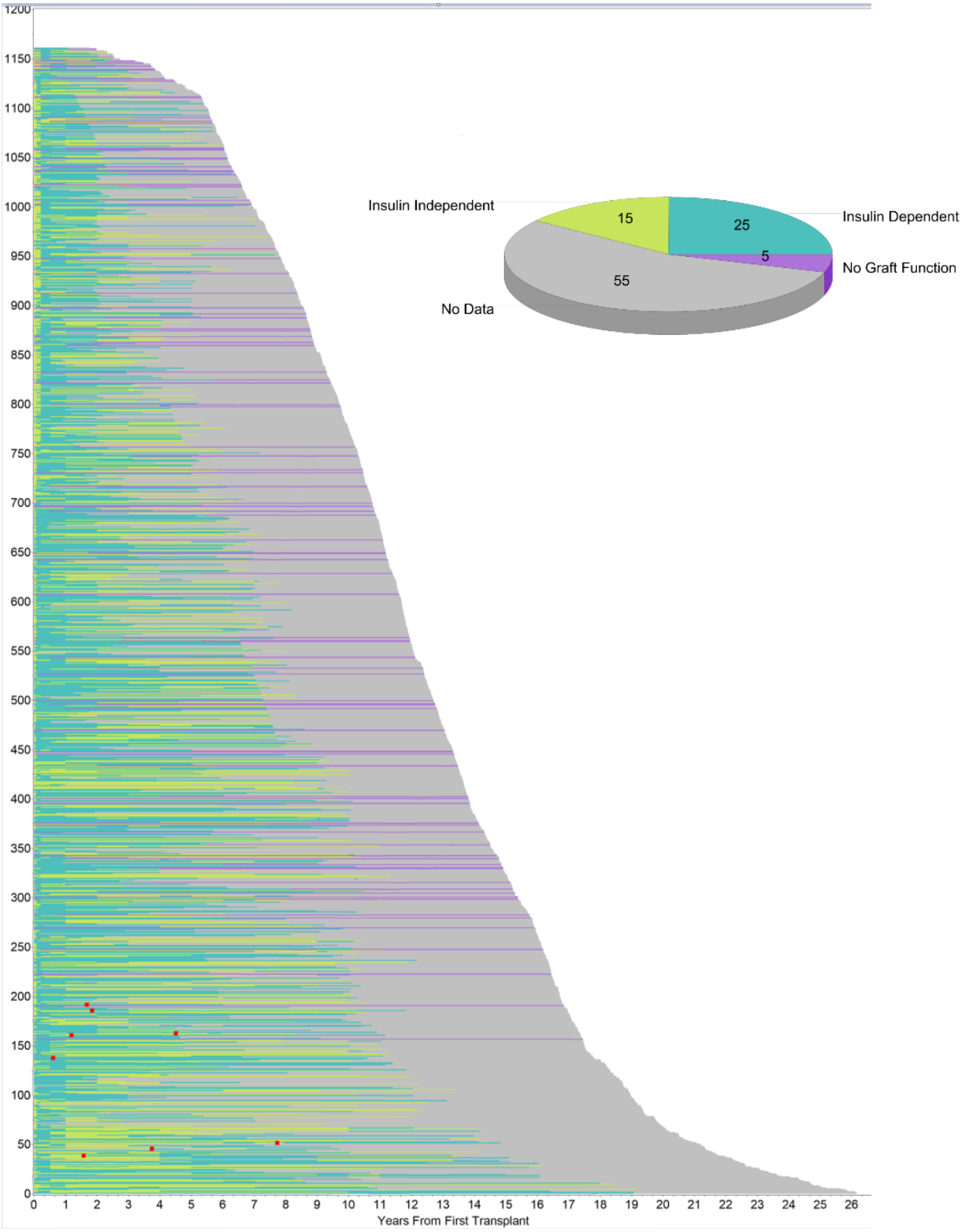

Collaborative Islet Transplant Registry 2025

Islet Autografts (N=1,320)
Yellow: insulin independent; Green: insulin-using with graft function; Purple: no islet function (Cpeptide<0.3 ng/ml); Gray: missing data; Red: re-infusions. Pie charts show percent of all follow-up time.

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CITR Coordinating Center A-3

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Chapter 1
Islet Transplant Activity

Introduction

This report is based on autologous islet transplant (Auto-Itx) recipients registered in the Collaborative Islet Transplant Registry (CITR), infused from 1999 through December 2023, with follow-up data through March 2025.

Of 26 North American sites performing Auto-ITx during this period, 15 reported data to CITR, along with 6 Eurasian and Australian islet transplant centers. These sites registered 1320 auto-islet transplant recipients. Of these, 1205 recipients were in North America, 98 in Europe/Asia, and 17 in Australia. One-hundred eighty-seven (187) were aged less than 18, and 1,133 were 18 or older at the time of their transplant. Nine (9) of the total recipients received a second auto -islet transplant. Exhibits 1-1A and 1-1B summarize the total autograft 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, there was an initial rise in annual transplants performed from 1999 through 2007, with subsequent leveling off thereafter. The light 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 at North American sites. Exhibit 1-4B shows the number of new Auto-Itx annually reported to CITR by the Eurasian 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
CITR Autograft Recipients by Continent and Age Group: Consented, Registered and First Infused in 1999-2023

Pediatric			Adult			
North America	Europe/Asia	Australia	North America	Europe/Asia	Australia	Total
179	0	8	1026	98	9	1320

Exhibit 1-1B
CITR Autograft Infusions by Continent and Age Group: Consented, Registered and First Infused in 1999-2023

Pediatric			Adult			
North America	Europe/Asia	Australia	North America	Europe/Asia	Australia	Total
182	0	8	1031	99	9	1329

Exhibit 1-2
Cumulative Auto-Islet Enrollment in CITR by Age Group

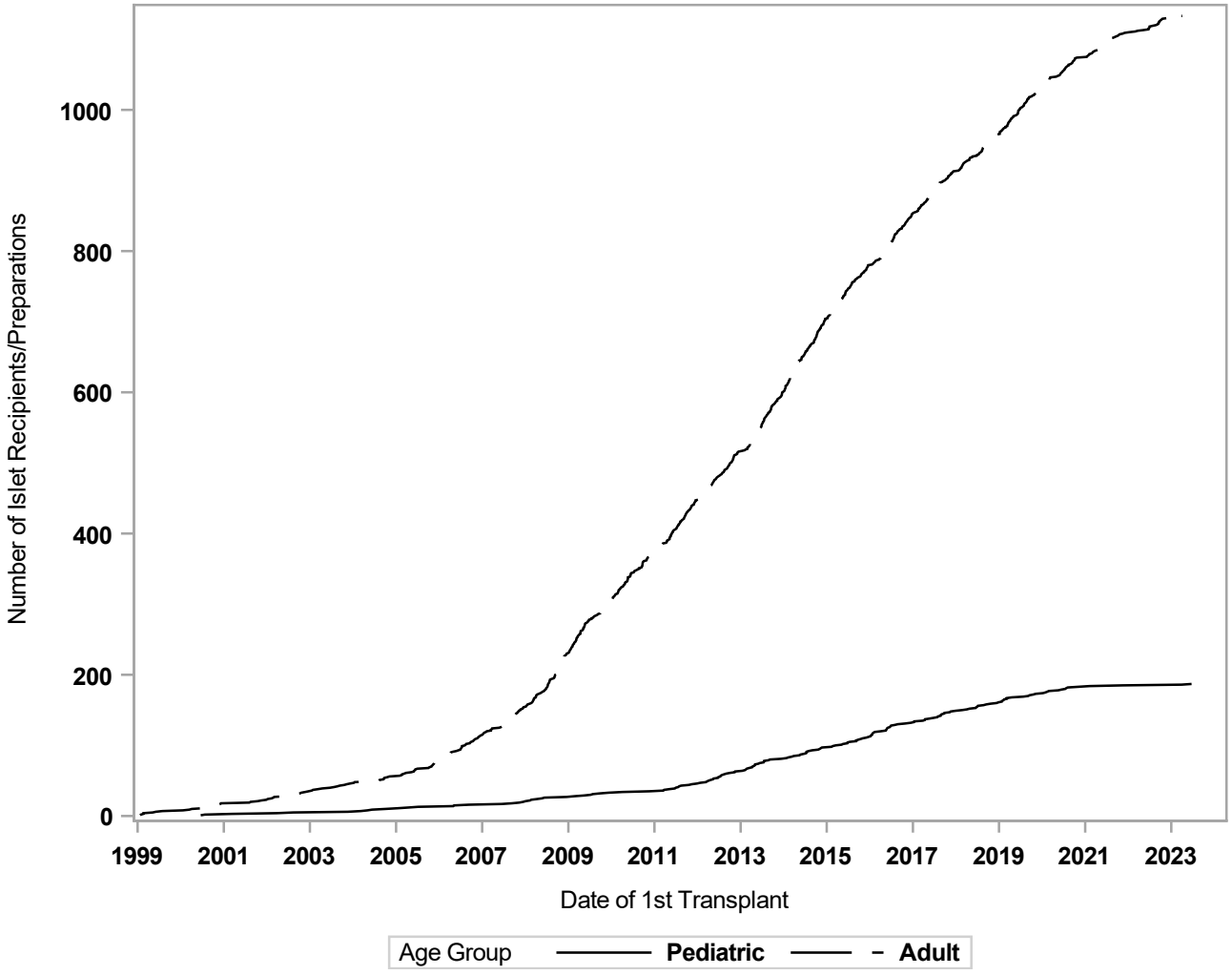
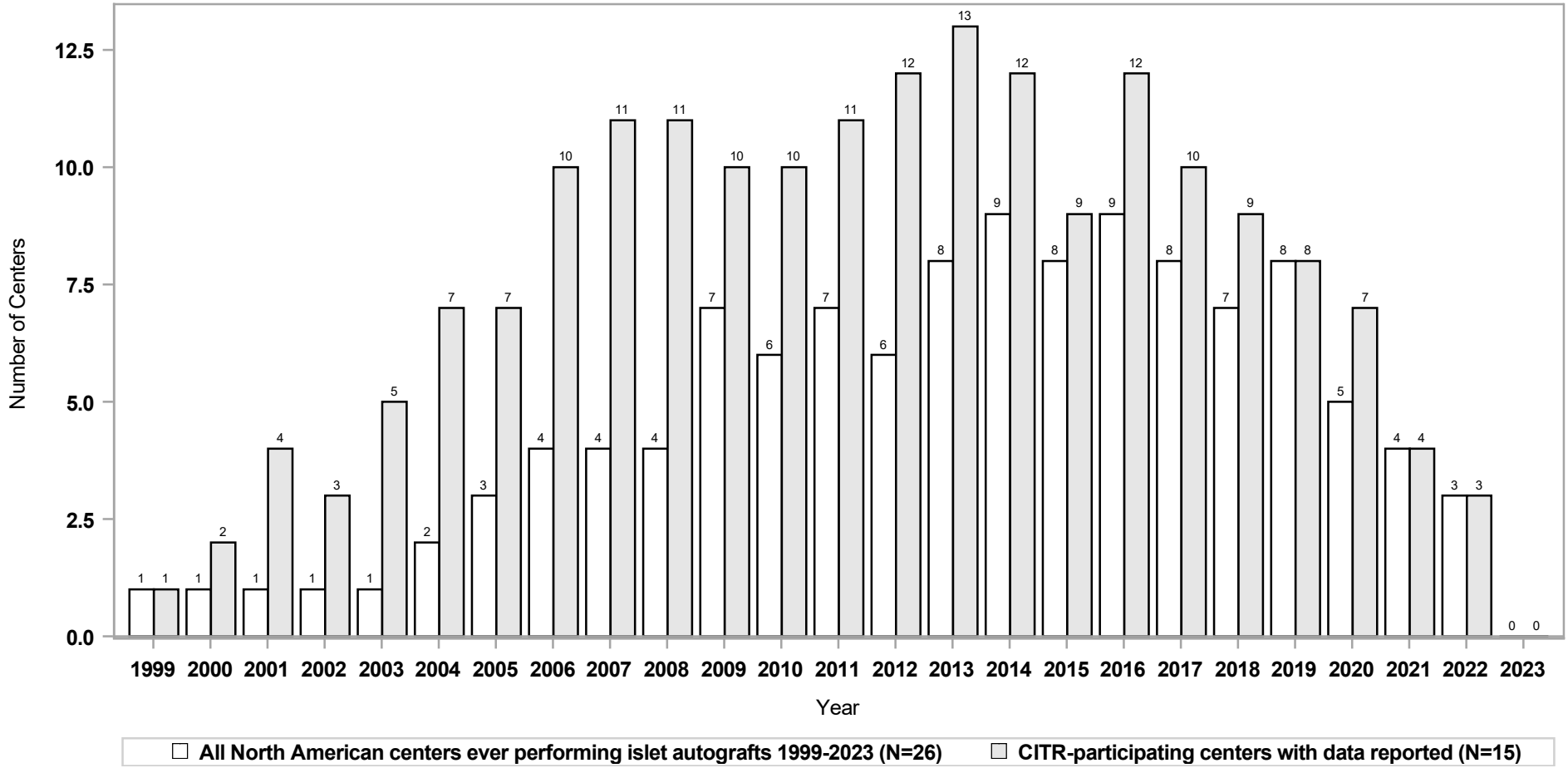


Exhibit 1-3
Number of Centers Performing Islet Autograft Transplants per Year and Number with Data Entered in CITR Database
All North American Centers 1999-2023



"All North American Centers Performing Islet Autografts" includes sites that reported performing at least one islet infusion procedure in the specified year.
"CITR-Participating Centers with Data Entered" represents the number of islet transplant programs in the specified year that have contributed data for the analyses included in this Report.

Exhibit 1 – 4A
Total Number of Islet Autograft Recipients Receiving Their First Islet Infusion and Number with Data Reported to CITR by Year:
Autograft recipients at CITR-Participating North American Islet Transplant Centers 1999-2023

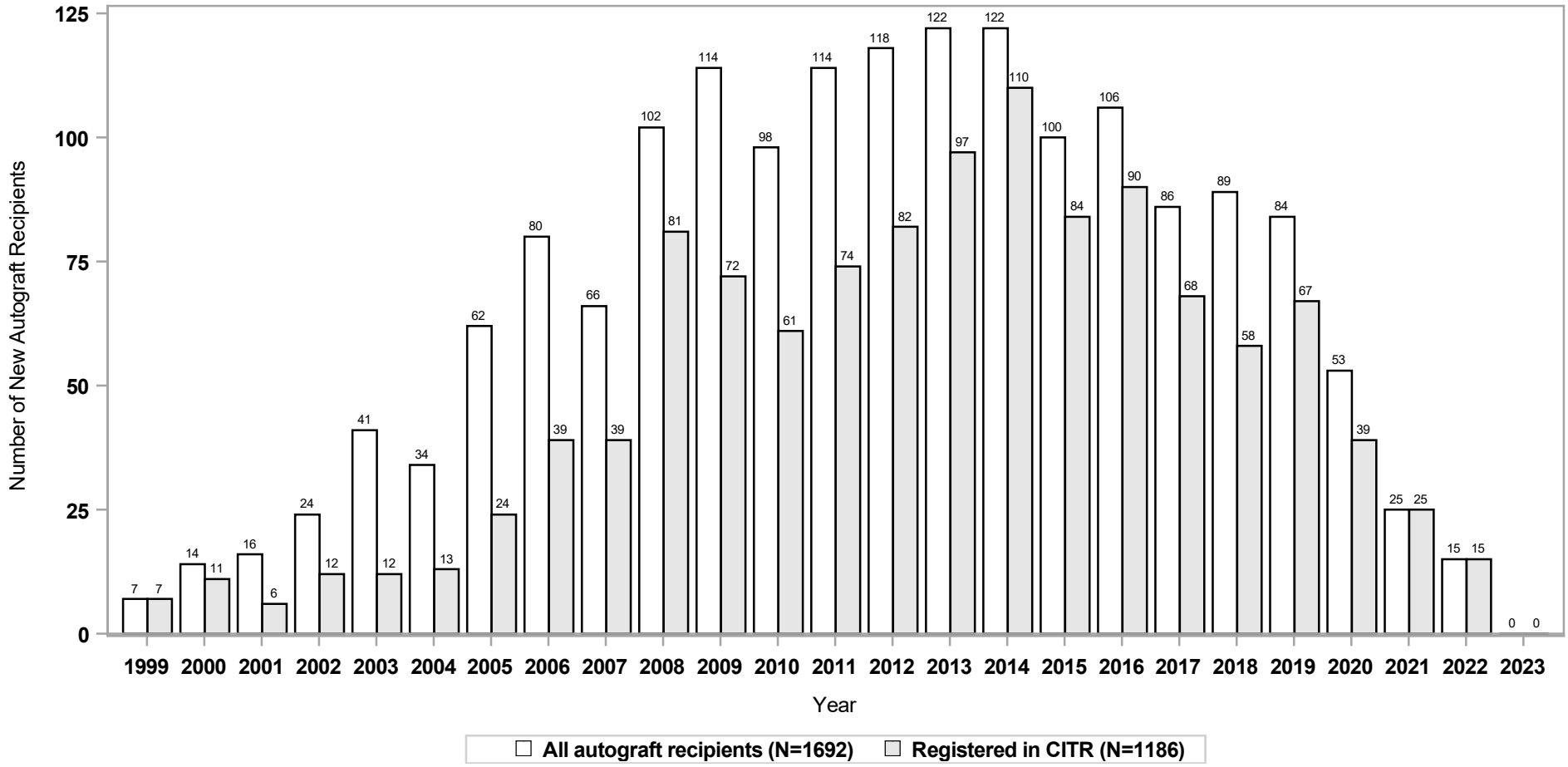


Exhibit 1 – 4B
Total Number of Islet Autograft Recipients Receiving Their First Islet Infusion and Number with Data Reported to CITR by Year:
Autograft recipients at CITR-Participating European, Australian, and Asian Islet Transplant Centers 1999-2023

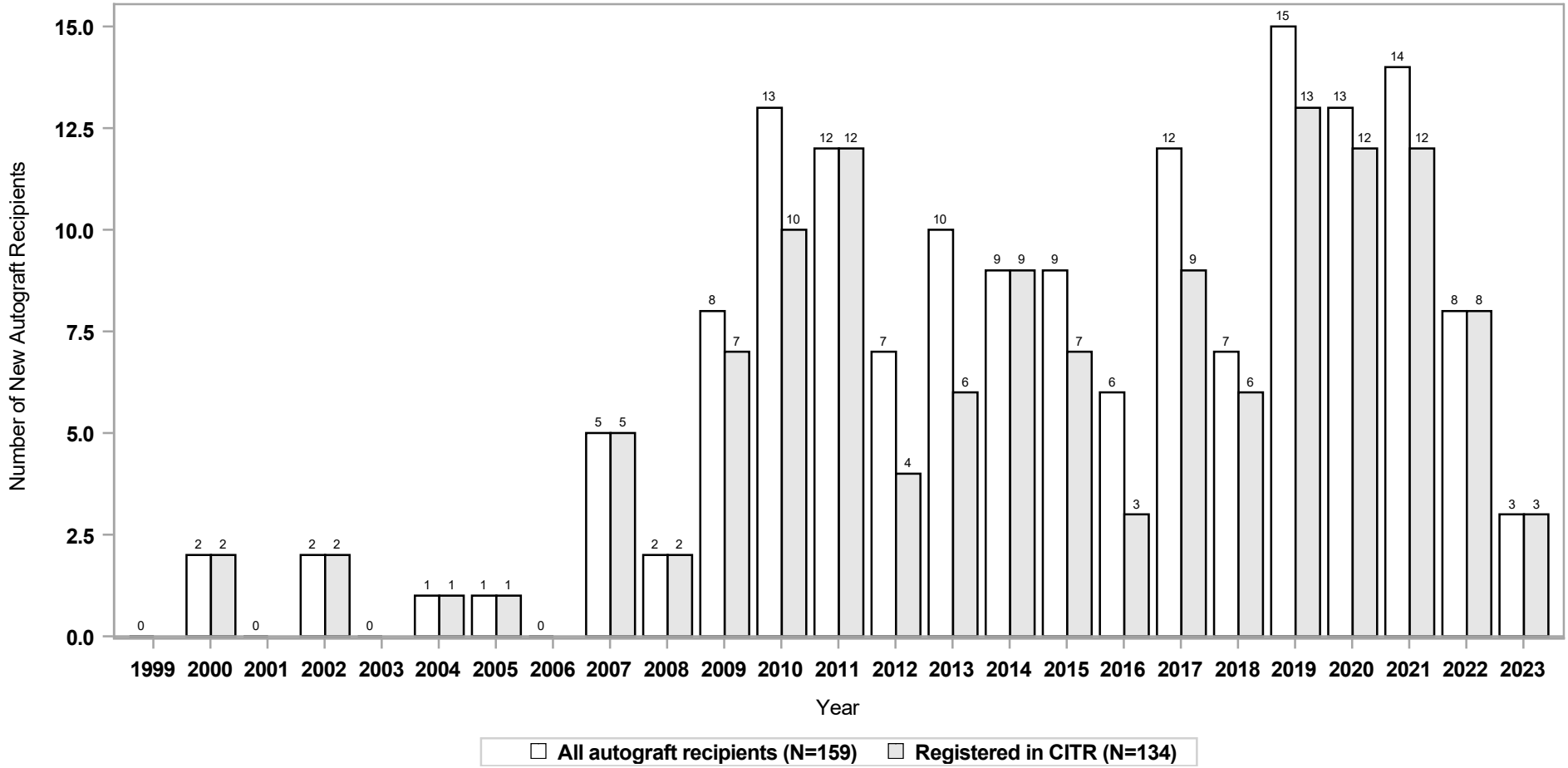


Exhibit 1 – 5
Islet Autograft Infusions by Infusion Sequence Number and Year:
CITR-Participating North American and International Centers, 1999-2025

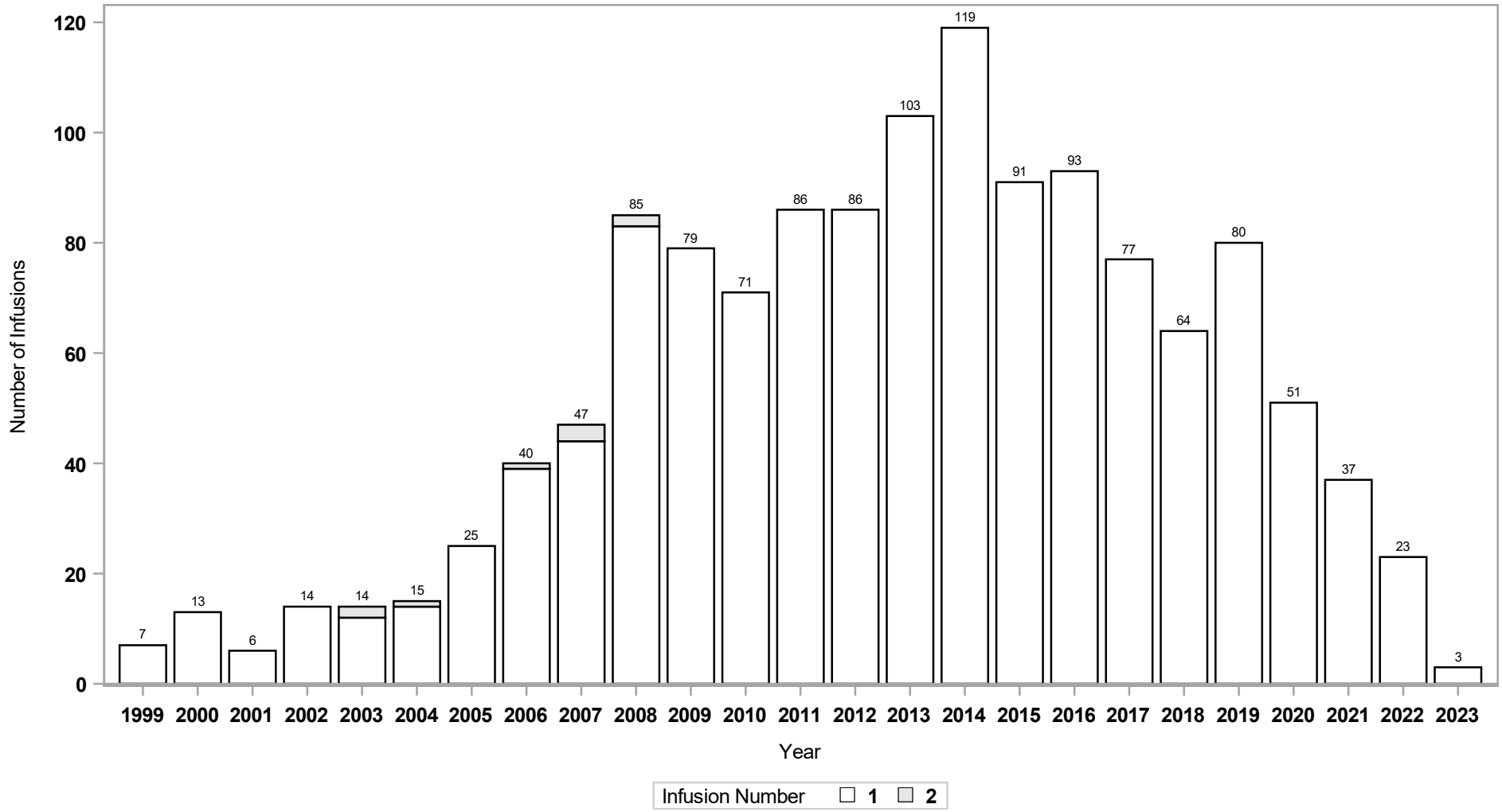
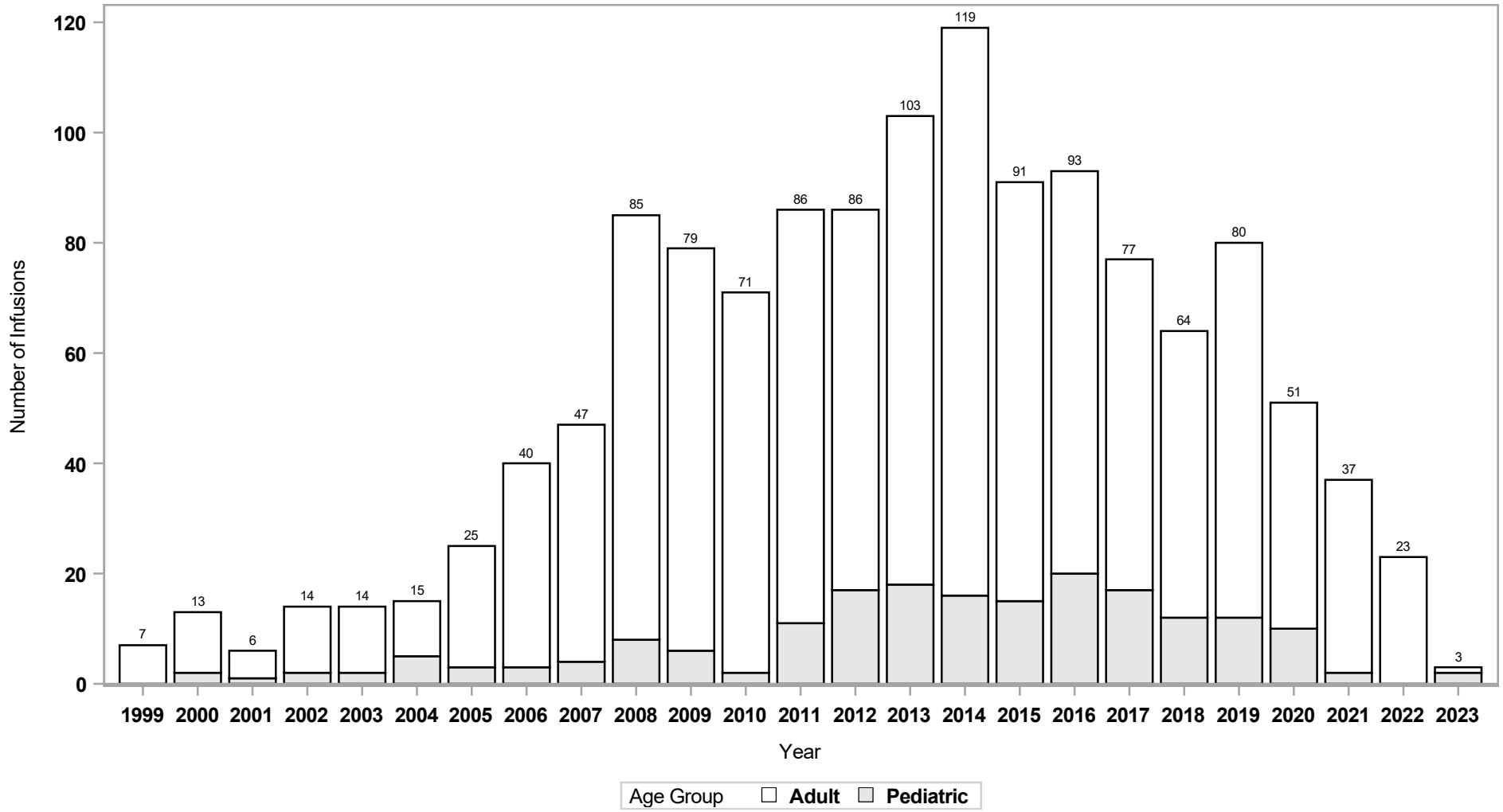


Exhibit 1 – 6
Islet Autograft Infusions by Age Group and Year:
CITR-Participating North American and International Centers, 1999-2025



Chapter 2
Recipient Characteristics

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.

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, or are unknown (Exhibit 2-1) across all age groups and eras.

Mean fasting blood glucose (FBG) was well in control, although it rose with increasing age (Exhibit 2-2A). 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 age groups and eras, 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, 3% of the 12-18 yo's required insulin, 3% of the the 18-<35 yo's required insulin, and 7% ≥35 yo's required insulin (Exhibit 2-2B).

Differences in FBG 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.

Total or completion pancreatectomy was done in 97% of the <35 yo's, and 88% of the ≥35 yo's. Across the eras, total pancreatectomy increased notably over the recent eras, likely reflecting the varying age distribution in the recent eras. (Exhibit 2-4)

Pancreatitis as the reason for the pancreatectomy declined from 96% in young children to 83% in ≥35 yo's (also reflected across the eras) (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.

Laboratory values are summarized by age group and era (Exhibit 2-5), with differences in laboratory values present in many cases across age groups.

Exhibit 2-1
Recipient Demographics

	Age Group (p=0.31)											
	<12 yrs (N[1]=69, Total [2]=69)			12-<18 yrs (N=118, Total=118)			18-<35 yrs (N=335, Total=335)			>=35 yrs (N=798, Total=798)		
Gender	n	% of N	% of Total	n	% of N	% of Total	n	% of N	% of Total	n	% of N	% of Total
Female	44	63.8	63.8	71	60.2	60.2	227	67.8	67.8	546	68.4	68.4
Male	25	36.2	36.2	47	39.8	39.8	108	32.2	32.2	252	31.6	31.6

	Era (p=0.40)											
	Era 1 1999-2006 (N=130, Total=130)			Era 2 2007-2014 (N=671, Total=671)			Era 3 2015-2022 (N=516, Total=516)			Era 4 2023-2030 (N=3, Total=3)		
Gender	n	% of N	% of Total	n	% of N	% of Total	n	% of N	% of Total	n	% of N	% of Total
Female	88	67.7	67.7	464	69.2	69.2	334	64.7	64.7	2	66.7	66.7
Male	42	32.3	32.3	207	30.8	30.8	182	35.3	35.3	1	33.3	33.3

[1] N = Recipients with data
[2] Total = Recipients of the given age group or receiving first transplant in the given era

Exhibit 2-1 (continued)
Recipient Demographics

	Age Group (p=<0.001)											
	<12 yrs (N[1]=69, Total [2]=69)			12-<18 yrs (N=118, Total=118)			18-<35 yrs (N=335, Total=335)			>=35 yrs (N=798, Total=798)		
Race	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
American Indian/Alaska Native	0	0.0	0.0	0	0.0	0.0	2	0.6	0.6	3	0.4	0.4
Asian	2	2.9	2.9	0	0.0	0.0	3	0.9	0.9	4	0.5	0.5
Black or African American	0	0.0	0.0	0	0.0	0.0	7	2.1	2.1	29	3.6	3.6
Multiple	1	1.4	1.4	1	0.8	0.8	0	0.0	0.0	0	0.0	0.0
Other	2	2.9	2.9	6	5.1	5.1	5	1.5	1.5	6	0.8	0.8
Unknown	57	82.6	82.6	84	71.2	71.2	181	54.0	54.0	332	41.6	41.6
White	7	10.1	10.1	27	22.9	22.9	137	40.9	40.9	424	53.1	53.1

[1] N = Recipients with data
[2] Total = Recipients of the given age group or receiving first transplant in the given era

Exhibit 2-1 (continued)
Recipient Demographics

	Era (p=<0.001)											
	Era 1 1999-2006 (N=130, Total=130)			Era 2 2007-2014 (N=671, Total=671)			Era 3 2015-2022 (N=516, Total=516)			Era 4 2023-2030 (N=3, Total=3)		
Race	n	% of N	% of Total	n	% of N	% of Total	n	% of N	% of Total	n	% of N	% of Total
American Indian/Alaska Native	0	0.0	0.0	3	0.4	0.4	2	0.4	0.4	0	0.0	0.0
Asian	1	0.8	0.8	1	0.1	0.1	7	1.4	1.4	0	0.0	0.0
Black or African American	2	1.5	1.5	18	2.7	2.7	16	3.1	3.1	0	0.0	0.0
Multiple	0	0.0	0.0	1	0.1	0.1	1	0.2	0.2	0	0.0	0.0
Other	0	0.0	0.0	3	0.4	0.4	14	2.7	2.7	2	66.7	66.7
Unknown	45	34.6	34.6	380	56.6	56.6	229	44.4	44.4	0	0.0	0.0
White	82	63.1	63.1	265	39.5	39.5	247	47.9	47.9	1	33.3	33.3

[1] N = Recipients with data
[2] Total = Recipients of the given age group or receiving first transplant in the given era

Exhibit 2-1 (continued)
Recipient Demographics

	Age Group (p=<0.05)											
	<12 yrs (N[1]=69, Total [2]=69)			12-<18 yrs (N=118, Total=118)			18-<35 yrs (N=335, Total=335)			>=35 yrs (N=798, Total=798)		
Ethnicity	n	% of N	% of Total	n	% of N	% of Total	n	% of N	% of Total	n	% of N	% of Total
Hispanic or Latino	0	0.0	0.0	5	4.2	4.2	5	1.5	1.5	13	1.6	1.6
Not Hispanic or Latino	12	17.4	17.4	29	24.6	24.6	145	43.3	43.3	450	56.4	56.4
Not reported	2	2.9	2.9	1	0.8	0.8	4	1.2	1.2	5	0.6	0.6
Unknown	55	79.7	79.7	83	70.3	70.3	181	54.0	54.0	330	41.4	41.4

	Era (p=0.15)											
	Era 1 1999-2006 (N=130, Total=130)			Era 2 2007-2014 (N=671, Total=671)			Era 3 2015-2022 (N=516, Total=516)			Era 4 2023-2030 (N=3, Total=3)		
Ethnicity	n	% of N	% of Total	n	% of N	% of Total	n	% of N	% of Total	n	% of N	% of Total
Hispanic or Latino	0	0.0	0.0	8	1.2	1.2	15	2.9	2.9	0	0.0	0.0
Not Hispanic or Latino	70	53.8	53.8	284	42.3	42.3	279	54.1	54.1	3	100.0	100.0
Not reported	1	0.8	0.8	6	0.9	0.9	5	1.0	1.0	0	0.0	0.0
Unknown	59	45.4	45.4	373	55.6	55.6	217	42.1	42.1	0	0.0	0.0

[1] N = Recipients with data
[2] Total = Recipients of the given age group or receiving first transplant in the given era

Exhibit 2-1 (continued)
Recipient Demographics

	Age Group (p=<0.001)											
	<12 yrs (N[1]=11, Total [2]=69)			12-<18 yrs (N=28, Total=118)			18-<35 yrs (N=102, Total=335)			>=35 yrs (N=349, Total=798)		
Employment	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
Employment status unknown	4	36.4	5.8	4	14.3	3.4	37	36.3	11.0	135	38.7	16.9
Not applicable, less than 5 years old	1	9.1	1.4	0	0.0	0.0	0	0.0	0.0	0	0.0	0.0
Not working by choice	0	0.0	0.0	0	0.0	0.0	3	2.9	0.9	13	3.7	1.6
Not working due to disease	0	0.0	0.0	0	0.0	0.0	23	22.5	6.9	74	21.2	9.3
Not working, reason unknown	0	0.0	0.0	0	0.0	0.0	8	7.8	2.4	14	4.0	1.8
Not working, unable to find employment	0	0.0	0.0	0	0.0	0.0	0	0.0	0.0	2	0.6	0.3
Retired	0	0.0	0.0	0	0.0	0.0	0	0.0	0.0	27	7.7	3.4
Student	6	54.5	8.7	24	85.7	20.3	10	9.8	3.0	0	0.0	0.0
Working full time	0	0.0	0.0	0	0.0	0.0	17	16.7	5.1	73	20.9	9.1
Working part time by choice	0	0.0	0.0	0	0.0	0.0	1	1.0	0.3	3	0.9	0.4
Working part time due to disease	0	0.0	0.0	0	0.0	0.0	3	2.9	0.9	6	1.7	0.8
Working part time, reason unknown	0	0.0	0.0	0	0.0	0.0	0	0.0	0.0	2	0.6	0.3
Missing	58	N/A	84.1	90	N/A	76.3	233	N/A	69.6	449	N/A	56.3

[1] N = Recipients with data
[2] Total = Recipients of the given age group or receiving first transplant in the given era

Exhibit 2-1 (continued)
Recipient Demographics

	Era (p=<0.001)											
	Era 1 1999-2006 (N=18, Total=130)			Era 2 2007-2014 (N=268, Total=671)			Era 3 2015-2022 (N=201, Total=516)			Era 4 2023-2030 (N=3, Total=3)		
Employment	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
Employment status unknown	6	33.3	4.6	93	34.7	13.9	81	40.3	15.7	0	0.0	0.0
Not applicable, less than 5 years old	0	0.0	0.0	0	0.0	0.0	0	0.0	0.0	1	33.3	33.3
Not working by choice	2	11.1	1.5	13	4.9	1.9	1	0.5	0.2	0	0.0	0.0
Not working due to disease	4	22.2	3.1	55	20.5	8.2	38	18.9	7.4	0	0.0	0.0
Not working, reason unknown	1	5.6	0.8	14	5.2	2.1	7	3.5	1.4	0	0.0	0.0
Not working, unable to find employment	0	0.0	0.0	0	0.0	0.0	2	1.0	0.4	0	0.0	0.0
Retired	2	11.1	1.5	16	6.0	2.4	9	4.5	1.7	0	0.0	0.0
Student	0	0.0	0.0	11	4.1	1.6	28	13.9	5.4	1	33.3	33.3
Working full time	3	16.7	2.3	55	20.5	8.2	31	15.4	6.0	1	33.3	33.3
Working part time by choice	0	0.0	0.0	4	1.5	0.6	0	0.0	0.0	0	0.0	0.0
Working part time due to disease	0	0.0	0.0	6	2.2	0.9	3	1.5	0.6	0	0.0	0.0
Working part time, reason unknown	0	0.0	0.0	1	0.4	0.1	1	0.5	0.2	0	0.0	0.0
Missing	112	N/A	86.2	403	N/A	60.1	315	N/A	61.0	0	N/A	0.0

[1] N = Recipients with data
[2] Total = Recipients of the given age group or receiving first transplant in the given era

Exhibit 2-2A
Recipient Characteristics at First Infusion

	Age Group												
	<12 years			12 - <18 years			18 - <35 years			>=35 years			
	N	Mean	STE	N	Mean	STE	N	Mean	STE	N	Mean	STE	p
Age at Transplant	69	8.3	0.3	118	15.3	0.2	335	27.2	0.3	798	48.5	0.3	<0.001
Weight (kg)	33	29.8	2.4	58	62	2.2	166	73.3	1.4	463	72.8	0.8	<0.001
Body Mass Index (kg/m ^{2})	9	17.2	0.7	25	24	1.1	114	25.9	0.6	354	25.6	0.3	<0.001
Daily Insulin Requirement Prior to Transplant (units)	62	0	0	108	0.5	0.3	279	1.4	0.6	641	1.8	0.4	0.219
Avg daily insulin/kg recipient body weight	28	0	0	49	0	0	136	0	0	377	0	0	0.383
Fasting plasma glucose (mg/dL)	51	88.7	1.3	86	89.2	1.2	209	94.3	1.3	466	102.4	1.5	<0.001
Basal C-Peptide (ng/mL)	50	1.4	0.2	84	2	0.1	230	2.1	0.1	542	2.2	0.1	0.002
HbA1C (%)	58	5.3	0.1	88	5.3	0.1	235	5.4	0.1	564	5.7	0	<0.001

Significant differences by age group and era are displayed in the following box-and-whisker plots.

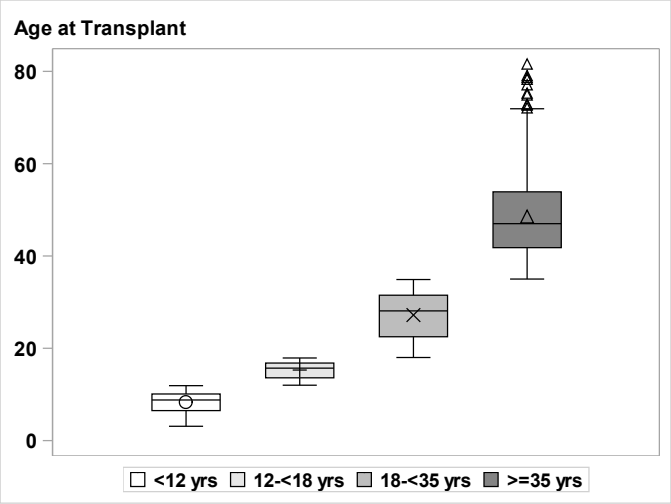
Exhibit 2-2A
Recipient Characteristics at First Infusion

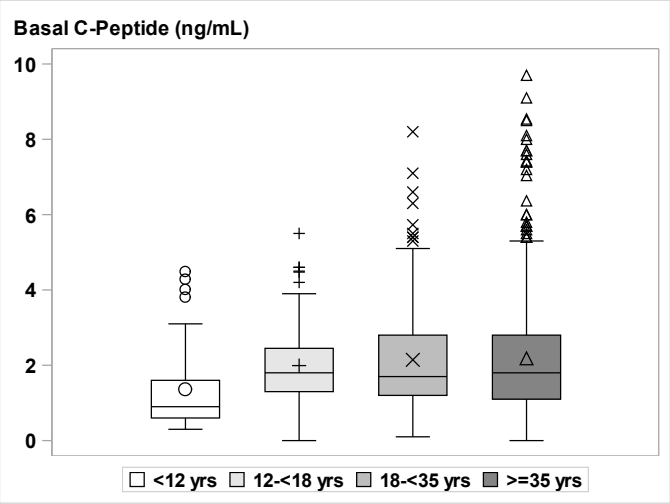
	Era												
	Era 1 1999-2006			Era 2 2007-2014			Era 3 2015-2022			Era 4 2023-2030			
	N	Mean	STE	N	Mean	STE	N	Mean	STE	N	Mean	STE	p
Age at Transplant	130	37.4	1.2	671	38.8	0.6	516	37.4	0.7	3	21.7	13.2	0.121
Weight (kg)	15	65.9	3.4	273	70.3	1	429	70.2	1	3	44.7	15.5	0.120
Body Mass Index (kg/m ^{2})	13	24	1.4	253	25	0.3	233	26	0.4	3	19.8	2.8	0.048
Daily Insulin Requirement Prior to Transplant (units)	102	0.5	0.4	586	1.2	0.3	399	2.1	0.5	3	0	0	0.254
Avg daily insulin/kg recipient body weight	7	0	0	211	0	0	369	0	0	3	0	0	0.935
Fasting plasma glucose (mg/dL)	15	93.3	1.9	442	95.4	1.3	352	101.8	1.4	3	75.3	3.4	0.003
Basal C-Peptide (ng/mL)	21	2.3	0.4	539	2	0.1	344	2.2	0.1	2	2.5	2	0.128
HbA1C (%)	29	5.2	0.1	533	5.5	0	381	5.6	0	2	5.3	0.2	0.008

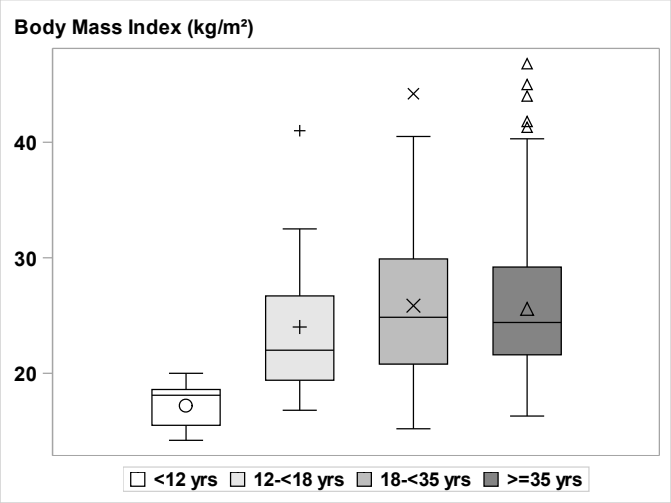
Significant differences by age group and era are displayed in the following box-and-whisker plots.

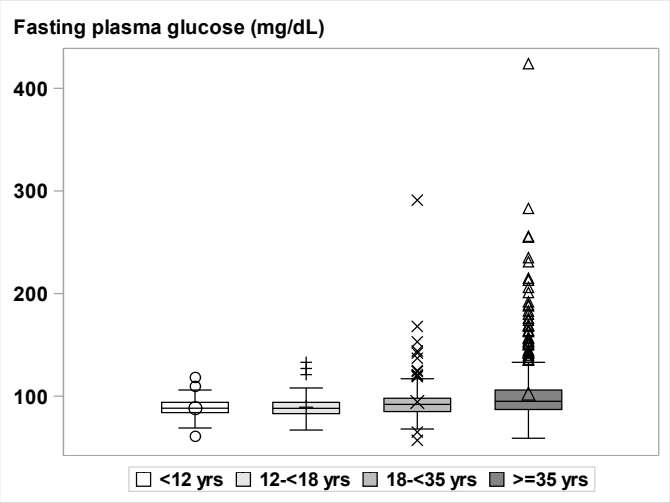
Exhibit 2-2A (continued)
Recipient Characteristics at First Infusion

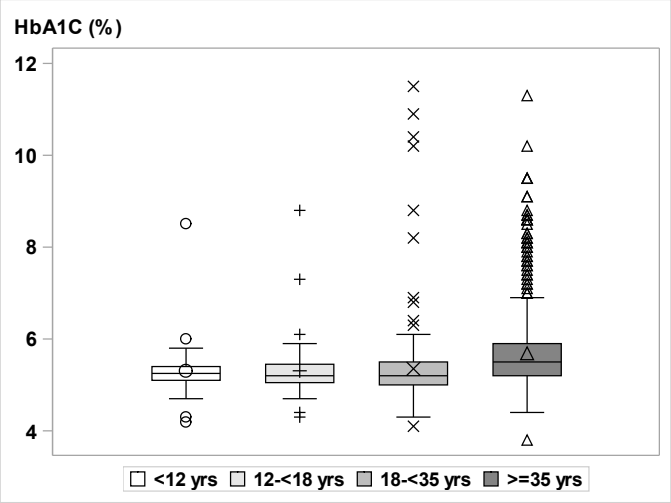
Significant trends in patient characteristics from table above by Age Group











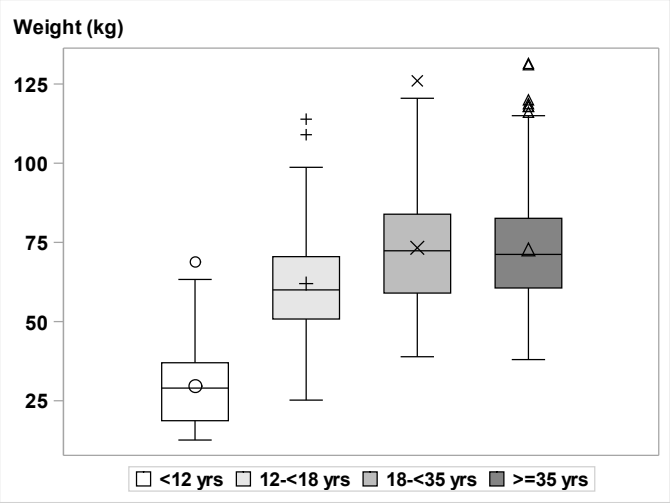
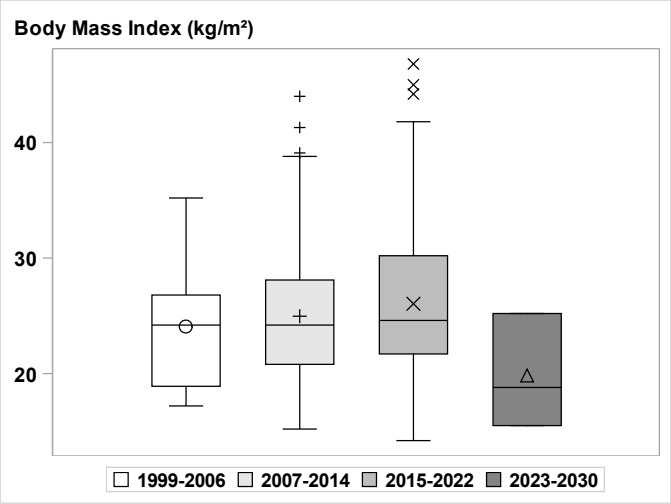
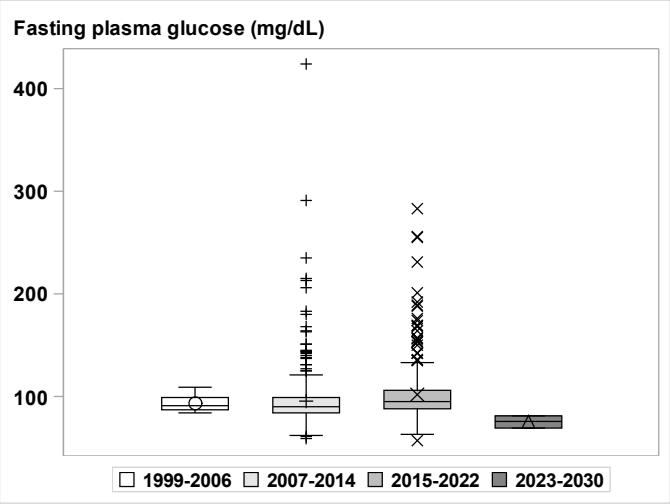


Exhibit 2-2A (continued)
Recipient Characteristics at First Infusion

Significant trends in patient characteristics from table above by Era





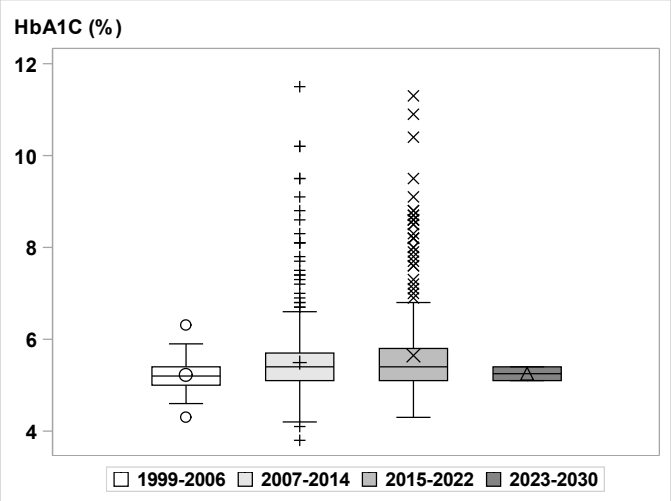


Exhibit 2-2B
Recipient Insulin Use at First Infusion

	Age Group											
	<12 yrs (N[1]=62, Total [2]=69)			12-<18 yrs (N=108, Total=118)			18-<35 yrs (N=279, Total=335)			>=35 yrs (N=641, Total=798)		
Baseline Insulin Use	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
Off	62	100.0	89.9	105	97.2	89.0	271	97.1	80.9	595	92.8	74.6
On	0	0.0	0.0	3	2.8	2.5	8	2.9	2.4	46	7.2	5.8
Missing	7	N/A	10.1	10	N/A	8.5	56	N/A	16.7	157	N/A	19.7

	Era											
	Era 1 1999-2006 (N=102, Total=130)			Era 2 2007-2014 (N=586, Total=671)			Era 3 2015-2022 (N=399, Total=516)			Era 4 2023-2030 (N=3, Total=3)		
Baseline Insulin Use	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
Off	100	98.0	76.9	558	95.2	83.2	372	93.2	72.1	3	100.0	100.0
On	2	2.0	1.5	28	4.8	4.2	27	6.8	5.2	0	0.0	0.0
Missing	28	N/A	21.5	85	N/A	12.7	117	N/A	22.7	0	N/A	0.0

[1] N = Recipients with data
[2] Total = Recipients of the given age group receiving first transplant in the given era

Exhibit 2-3
Recipient Characteristics and Medical History

	Age Group (p=0.73)											
	<12 yrs (N[1]=17, Total [2]=69)			12-<18 yrs (N=35, Total=118)			18-<35 yrs (N=118, Total=335)			>=35 yrs (N=352, Total=798)		
Hypoglycemia Status	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
Having episodes and aware	0	0.0	0.0	1	2.9	0.8	1	0.8	0.3	12	3.4	1.5
No Occurrence	17	100.0	24.6	34	97.1	28.8	115	97.5	34.3	336	95.5	42.1
Unawareness	0	0.0	0.0	0	0.0	0.0	2	1.7	0.6	4	1.1	0.5
Missing	52	N/A	75.4	83	N/A	70.3	217	N/A	64.8	446	N/A	55.9

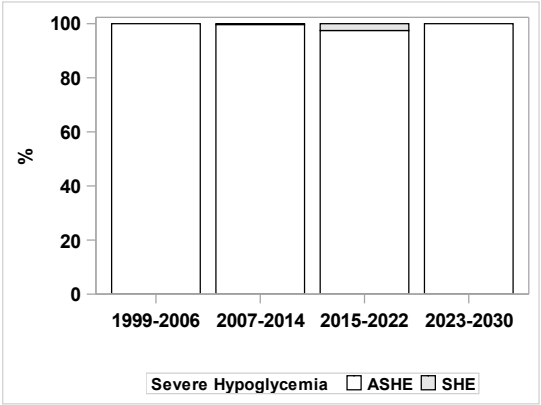
	Era (p=0.09)											
	Era 1 1999-2006 (N=16, Total=130)			Era 2 2007-2014 (N=335, Total=671)			Era 3 2015-2022 (N=169, Total=516)			Era 4 2023-2030 (N=2, Total=3)		
Hypoglycemia Status	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
Having episodes and aware	0	0.0	0.0	5	1.5	0.7	9	5.3	1.7	0	0.0	0.0
No Occurrence	16	100.0	12.3	324	96.7	48.3	160	94.7	31.0	2	100.0	66.7
Unawareness	0	0.0	0.0	6	1.8	0.9	0	0.0	0.0	0	0.0	0.0
Missing	114	N/A	87.7	336	N/A	50.1	347	N/A	67.2	1	N/A	33.3

[1] N = Recipients with data
[2] Total = Recipients of the given age group or receiving first transplant in the given era

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

	Age Group (p=0.05)											
	<12 yrs (N[1]=45, Total [2]=69)			12-<18 yrs (N=93, Total=118)			18-<35 yrs (N=258, Total=335)			>=35 yrs (N=642, Total=798)		
Severe Hypoglycemia	n	% of N	% of Total	n	% of N	% of Total	n	% of N	% of Total	n	% of N	% of Total
ASHE	45	100.0	65.2	90	96.8	76.3	258	100.0	77.0	636	99.1	79.7
SHE	0	0.0	0.0	3	3.2	2.5	0	0.0	0.0	6	0.9	0.8
Missing	24	N/A	34.8	25	N/A	21.2	77	N/A	23.0	156	N/A	19.5

	Era (p=<0.05)											
	Era 1 1999-2006 (N=124, Total=130)			Era 2 2007-2014 (N=634, Total=671)			Era 3 2015-2022 (N=277, Total=516)			Era 4 2023-2030 (N=3, Total=3)		
Severe Hypoglycemia	n	% of N	% of Total	n	% of N	% of Total	n	% of N	% of Total	n	% of N	% of Total
ASHE	124	100.0	95.4	632	99.7	94.2	270	97.5	52.3	3	100.0	100.0
SHE	0	0.0	0.0	2	0.3	0.3	7	2.5	1.4	0	0.0	0.0
Missing	6	N/A	4.6	37	N/A	5.5	239	N/A	46.3	0	N/A	0.0

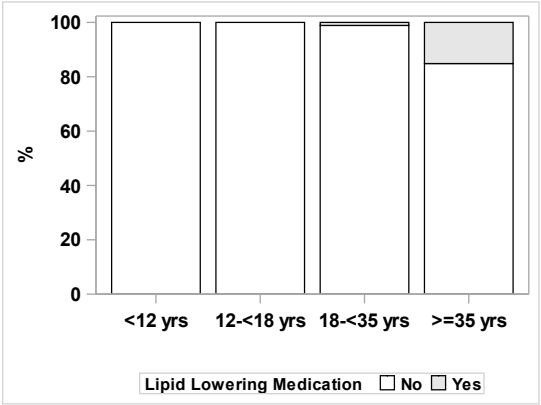


[1] N = Recipients with data
[2] Total = Recipients of the given age group or receiving first transplant in the given era

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

	Age Group (p=<0.001)											
	<12 yrs (N[1]=8, Total [2]=69)			12-<18 yrs (N=20, Total=118)			18-<35 yrs (N=90, Total=335)			>=35 yrs (N=284, Total=798)		
Lipid Lowering Medication	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	8	100.0	11.6	20	100.0	16.9	89	98.9	26.6	241	84.9	30.2
Yes	0	0.0	0.0	0	0.0	0.0	1	1.1	0.3	43	15.1	5.4
Missing	61	N/A	88.4	98	N/A	83.1	245	N/A	73.1	514	N/A	64.4

	Era (p=0.16)											
	Era 1 1999-2006 (N=7, Total=130)			Era 2 2007-2014 (N=218, Total=671)			Era 3 2015-2022 (N=175, Total=516)			Era 4 2023-2030 (N=2, Total=3)		
Lipid Lowering Medication	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	6	85.7	4.6	188	86.2	28.0	162	92.6	31.4	2	100.0	66.7
Yes	1	14.3	0.8	30	13.8	4.5	13	7.4	2.5	0	0.0	0.0
Missing	123	N/A	94.6	453	N/A	67.5	341	N/A	66.1	1	N/A	33.3

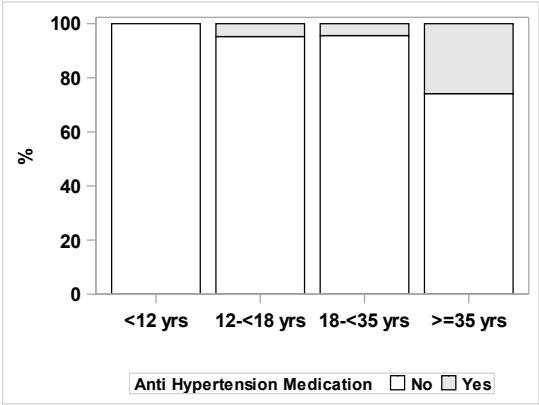


[1] N = Recipients with data
[2] Total = Recipients of the given age group or receiving first transplant in the given era

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

	Age Group (p=<0.001)											
	<12 yrs (N[1]=8, Total [2]=69)			12-<18 yrs (N=21, Total=118)			18-<35 yrs (N=91, Total=335)			>=35 yrs (N=286, Total=798)		
Anti Hypertension Medication	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	8	100.0	11.6	20	95.2	16.9	87	95.6	26.0	212	74.1	26.6
Yes	0	0.0	0.0	1	4.8	0.8	4	4.4	1.2	74	25.9	9.3
Missing	61	N/A	88.4	97	N/A	82.2	244	N/A	72.8	512	N/A	64.2

	Era (p=0.13)											
	Era 1 1999-2006 (N=7, Total=130)			Era 2 2007-2014 (N=220, Total=671)			Era 3 2015-2022 (N=177, Total=516)			Era 4 2023-2030 (N=2, Total=3)		
Anti Hypertension Medication	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	6	85.7	4.6	168	76.4	25.0	151	85.3	29.3	2	100.0	66.7
Yes	1	14.3	0.8	52	23.6	7.7	26	14.7	5.0	0	0.0	0.0
Missing	123	N/A	94.6	451	N/A	67.2	339	N/A	65.7	1	N/A	33.3



[1] N = Recipients with data
[2] Total = Recipients of the given age group or receiving first transplant in the given era

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

	Age Group (p=0.48)											
	<12 yrs (N[1]=7, Total [2]=69)			12-<18 yrs (N=23, Total=118)			18-<35 yrs (N=99, Total=335)			>=35 yrs (N=323, Total=798)		
Anti Hyperglycemia Medication	n	% of N	% of Total	n	% of N	% of Total	n	% of N	% of Total	n	% of N	% of Total
No	7	100.0	10.1	22	95.7	18.6	94	94.9	28.1	292	90.4	36.6
Yes	0	0.0	0.0	1	4.3	0.8	5	5.1	1.5	31	9.6	3.9
Missing	62	N/A	89.9	95	N/A	80.5	236	N/A	70.4	475	N/A	59.5

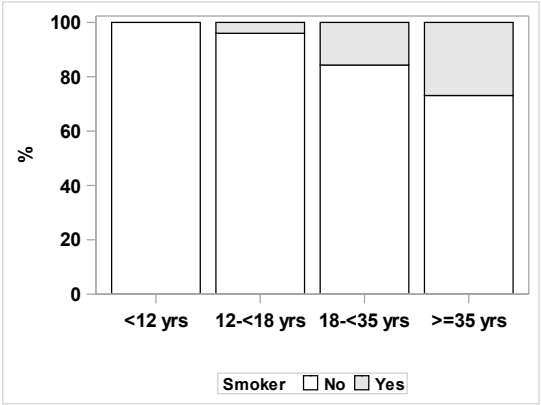
	Era (p=0.89)											
	Era 1 1999-2006 (N=7, Total=130)			Era 2 2007-2014 (N=225, Total=671)			Era 3 2015-2022 (N=217, Total=516)			Era 4 2023-2030 (N=3, Total=3)		
Anti Hyperglycemia Medication	n	% of N	% of Total	n	% of N	% of Total	n	% of N	% of Total	n	% of N	% of Total
No	7	100.0	5.4	205	91.1	30.6	200	92.2	38.8	3	100.0	100.0
Yes	0	0.0	0.0	20	8.9	3.0	17	7.8	3.3	0	0.0	0.0
Missing	123	N/A	94.6	446	N/A	66.5	299	N/A	57.9	0	N/A	0.0

[1] N = Recipients with data
[2] Total = Recipients of the given age group or receiving first transplant in the given era

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

	Age Group (p=<0.01)											
	<12 yrs (N[1]=11, Total [2]=69)			12-<18 yrs (N=25, Total=118)			18-<35 yrs (N=102, Total=335)			>=35 yrs (N=342, Total=798)		
Smoker	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	11	100.0	15.9	24	96.0	20.3	86	84.3	25.7	250	73.1	31.3
Yes	0	0.0	0.0	1	4.0	0.8	16	15.7	4.8	92	26.9	11.5
Missing	58	N/A	84.1	93	N/A	78.8	233	N/A	69.6	456	N/A	57.1

	Era (p=0.20)											
	Era 1 1999-2006 (N=14, Total=130)			Era 2 2007-2014 (N=263, Total=671)			Era 3 2015-2022 (N=200, Total=516)			Era 4 2023-2030 (N=3, Total=3)		
Smoker	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	10	71.4	7.7	195	74.1	29.1	163	81.5	31.6	3	100.0	100.0
Yes	4	28.6	3.1	68	25.9	10.1	37	18.5	7.2	0	0.0	0.0
Missing	116	N/A	89.2	408	N/A	60.8	316	N/A	61.2	0	N/A	0.0



[1] N = Recipients with data
[2] Total = Recipients of the given age group or receiving first transplant in the given era

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

	Age Group (p=0.11)											
	<12 yrs (N[1]=6, Total [2]=69)			12-<18 yrs (N=18, Total=118)			18-<35 yrs (N=83, Total=335)			>=35 yrs (N=304, Total=798)		
CAD History	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	6	100.0	8.7	17	94.4	14.4	83	100.0	24.8	289	95.1	36.2
Yes	0	0.0	0.0	1	5.6	0.8	0	0.0	0.0	15	4.9	1.9
Missing	63	N/A	91.3	100	N/A	84.7	252	N/A	75.2	494	N/A	61.9

	Era (p=0.81)											
	Era 1 1999-2006 (N=16, Total=130)			Era 2 2007-2014 (N=235, Total=671)			Era 3 2015-2022 (N=159, Total=516)			Era 4 2023-2030 (N=1, Total=3)		
CAD History	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	16	100.0	12.3	224	95.3	33.4	154	96.9	29.8	1	100.0	33.3
Yes	0	0.0	0.0	11	4.7	1.6	5	3.1	1.0	0	0.0	0.0
Missing	114	N/A	87.7	436	N/A	65.0	357	N/A	69.2	2	N/A	66.7

[1] N = Recipients with data
[2] Total = Recipients of the given age group or receiving first transplant in the given era

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

	Age Group (p=0.51)											
	<12 yrs (N[1]=6, Total [2]=69)			12-<18 yrs (N=18, Total=118)			18-<35 yrs (N=84, Total=335)			>=35 yrs (N=305, Total=798)		
CVA History	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	6	100.0	8.7	18	100.0	15.3	84	100.0	25.1	297	97.4	37.2
Yes	0	0.0	0.0	0	0.0	0.0	0	0.0	0.0	8	2.6	1.0
Missing	63	N/A	91.3	100	N/A	84.7	251	N/A	74.9	493	N/A	61.8

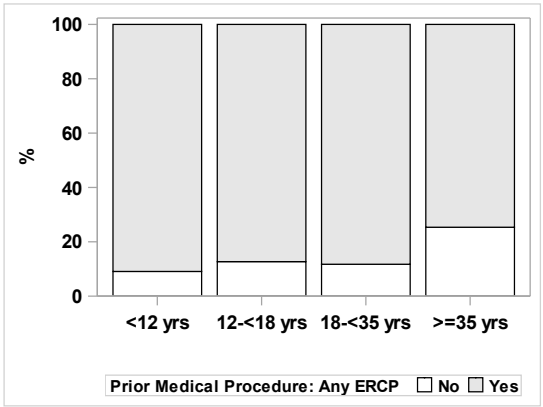
	Era (p=0.05)											
	Era 1 1999-2006 (N=16, Total=130)			Era 2 2007-2014 (N=236, Total=671)			Era 3 2015-2022 (N=160, Total=516)			Era 4 2023-2030 (N=1, Total=3)		
CVA History	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	15	93.8	11.5	229	97.0	34.1	160	100.0	31.0	1	100.0	33.3
Yes	1	6.3	0.8	7	3.0	1.0	0	0.0	0.0	0	0.0	0.0
Missing	114	N/A	87.7	435	N/A	64.8	356	N/A	69.0	2	N/A	66.7

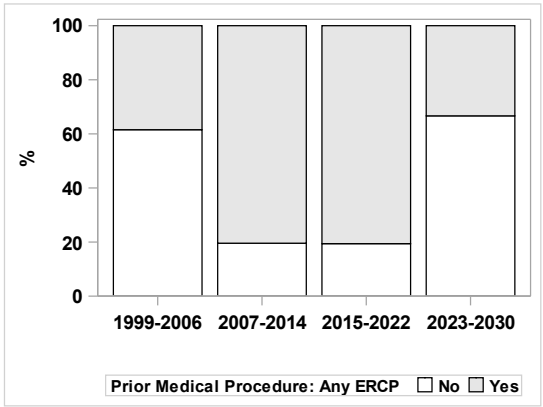
[1] N = Recipients with data
[2] Total = Recipients of the given age group or receiving first transplant in the given era

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

	Age Group (p=<0.001)											
	<12 yrs (N[1]=22, Total [2]=69)			12-<18 yrs (N=63, Total=118)			18-<35 yrs (N=196, Total=335)			>=35 yrs (N=489, Total=798)		
Prior Medical Procedure: Any ERCP	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	2	9.1	2.9	8	12.7	6.8	23	11.7	6.9	124	25.4	15.5
Yes	20	90.9	29.0	55	87.3	46.6	173	88.3	51.6	365	74.6	45.7
Missing	47	N/A	68.1	55	N/A	46.6	139	N/A	41.5	309	N/A	38.7

	Era (p=<0.01)											
	Era 1 1999-2006 (N=13, Total=130)			Era 2 2007-2014 (N=419, Total=671)			Era 3 2015-2022 (N=335, Total=516)			Era 4 2023-2030 (N=3, Total=3)		
Prior Medical Procedure: Any ERCP	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	8	61.5	6.2	82	19.6	12.2	65	19.4	12.6	2	66.7	66.7
Yes	5	38.5	3.8	337	80.4	50.2	270	80.6	52.3	1	33.3	33.3
Missing	117	N/A	90.0	252	N/A	37.6	181	N/A	35.1	0	N/A	0.0



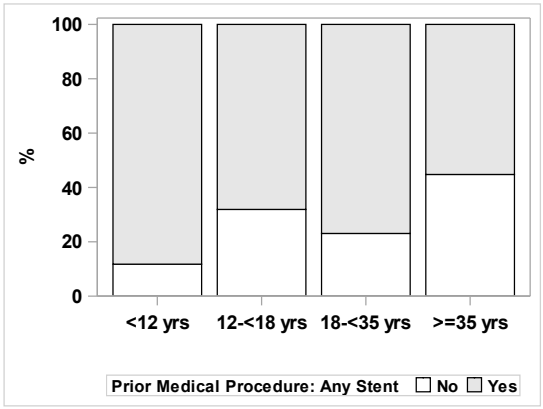


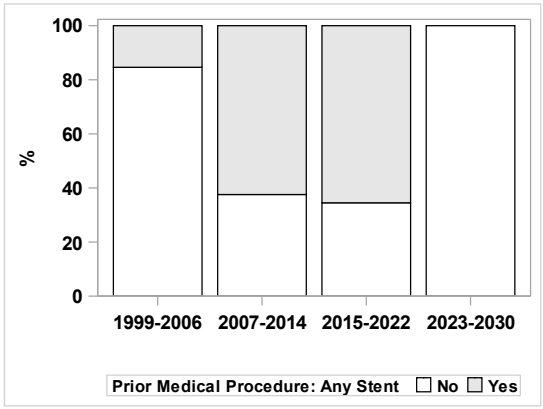
[1] N = Recipients with data
[2] Total = Recipients of the given age group or receiving first transplant in the given era

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

	Age Group (p=<0.001)											
	<12 yrs (N[1]=17, Total [2]=69)			12-<18 yrs (N=47, Total=118)			18-<35 yrs (N=156, Total=335)			>=35 yrs (N=402, Total=798)		
Prior Medical Procedure: Any Stent	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	2	11.8	2.9	15	31.9	12.7	36	23.1	10.7	180	44.8	22.6
Yes	15	88.2	21.7	32	68.1	27.1	120	76.9	35.8	222	55.2	27.8
Missing	52	N/A	75.4	71	N/A	60.2	179	N/A	53.4	396	N/A	49.6

	Era (p=<0.001)											
	Era 1 1999-2006 (N=13, Total=130)			Era 2 2007-2014 (N=322, Total=671)			Era 3 2015-2022 (N=284, Total=516)			Era 4 2023-2030 (N=3, Total=3)		
Prior Medical Procedure: Any Stent	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	11	84.6	8.5	121	37.6	18.0	98	34.5	19.0	3	100.0	100.0
Yes	2	15.4	1.5	201	62.4	30.0	186	65.5	36.0	0	0.0	0.0
Missing	117	N/A	90.0	349	N/A	52.0	232	N/A	45.0	0	N/A	0.0



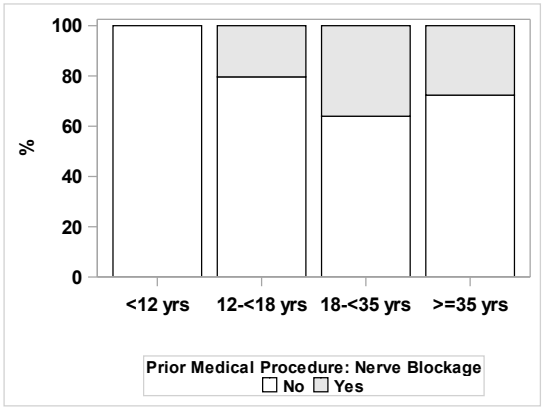


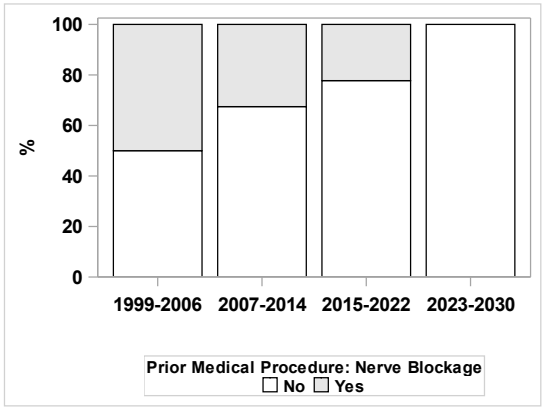
[1] N = Recipients with data
[2] Total = Recipients of the given age group or receiving first transplant in the given era

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

	Age Group (p=<0.001)											
	<12 yrs (N[1]=30, Total [2]=69)			12-<18 yrs (N=54, Total=118)			18-<35 yrs (N=161, Total=335)			>=35 yrs (N=427, Total=798)		
Prior Medical Procedure: Nerve Blockage	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	30	100.0	43.5	43	79.6	36.4	103	64.0	30.7	309	72.4	38.7
Yes	0	0.0	0.0	11	20.4	9.3	58	36.0	17.3	118	27.6	14.8
Missing	39	N/A	56.5	64	N/A	54.2	174	N/A	51.9	371	N/A	46.5

	Era (p=<0.001)											
	Era 1 1999-2006 (N=28, Total=130)			Era 2 2007-2014 (N=295, Total=671)			Era 3 2015-2022 (N=346, Total=516)			Era 4 2023-2030 (N=3, Total=3)		
Prior Medical Procedure: Nerve Blockage	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	14	50.0	10.8	199	67.5	29.7	269	77.7	52.1	3	100.0	100.0
Yes	14	50.0	10.8	96	32.5	14.3	77	22.3	14.9	0	0.0	0.0
Missing	102	N/A	78.5	376	N/A	56.0	170	N/A	32.9	0	N/A	0.0



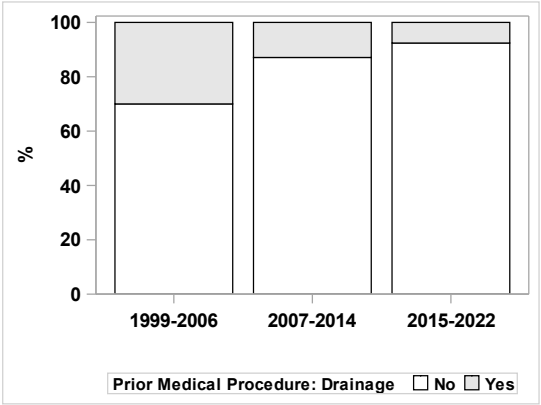


[1] N = Recipients with data
[2] Total = Recipients of the given age group or receiving first transplant in the given era

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

	Age Group (p=0.14)											
	<12 yrs (N[1]=6, Total [2]=69)			12-<18 yrs (N=21, Total=118)			18-<35 yrs (N=82, Total=335)			>=35 yrs (N=304, Total=798)		
Prior Medical Procedure: Drainage	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	5	83.3	7.2	16	76.2	13.6	76	92.7	22.7	267	87.8	33.5
Yes	1	16.7	1.4	5	23.8	4.2	6	7.3	1.8	37	12.2	4.6
Missing	63	N/A	91.3	97	N/A	82.2	253	N/A	75.5	494	N/A	61.9

	Era (p=<0.05)											
	Era 1 1999-2006 (N=20, Total=130)			Era 2 2007-2014 (N=248, Total=671)			Era 3 2015-2022 (N=145, Total=516)			Era 4 2023-2030 (N=., Total=3)		
Prior Medical Procedure: Drainage	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	14	70.0	10.8	216	87.1	32.2	134	92.4	26.0	0	.	0.0
Yes	6	30.0	4.6	32	12.9	4.8	11	7.6	2.1	0	.	0.0
Missing	110	N/A	84.6	423	N/A	63.0	371	N/A	71.9	3	N/A	100.0

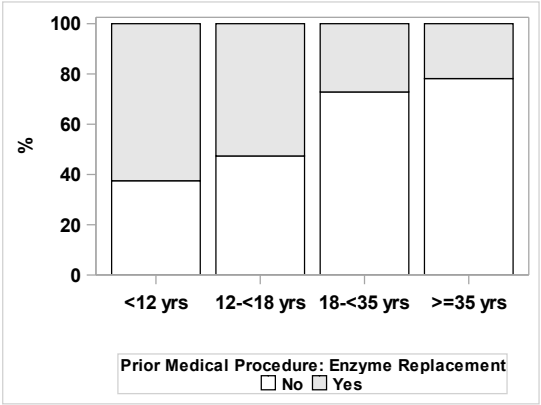


[1] N = Recipients with data
[2] Total = Recipients of the given age group or receiving first transplant in the given era

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

	Age Group (p=<0.01)											
	<12 yrs (N[1]=8, Total [2]=69)			12-<18 yrs (N=19, Total=118)			18-<35 yrs (N=81, Total=335)			>=35 yrs (N=316, Total=798)		
Prior Medical Procedure: Enzyme Replacement	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	3	37.5	4.3	9	47.4	7.6	59	72.8	17.6	247	78.2	31.0
Yes	5	62.5	7.2	10	52.6	8.5	22	27.2	6.6	69	21.8	8.6
Missing	61	N/A	88.4	99	N/A	83.9	254	N/A	75.8	482	N/A	60.4

	Era (p=0.10)											
	Era 1 1999-2006 (N=15, Total=130)			Era 2 2007-2014 (N=236, Total=671)			Era 3 2015-2022 (N=170, Total=516)			Era 4 2023-2030 (N=3, Total=3)		
Prior Medical Procedure: Enzyme Replacement	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	10	66.7	7.7	185	78.4	27.6	122	71.8	23.6	1	33.3	33.3
Yes	5	33.3	3.8	51	21.6	7.6	48	28.2	9.3	2	66.7	66.7
Missing	115	N/A	88.5	435	N/A	64.8	346	N/A	67.1	0	N/A	0.0

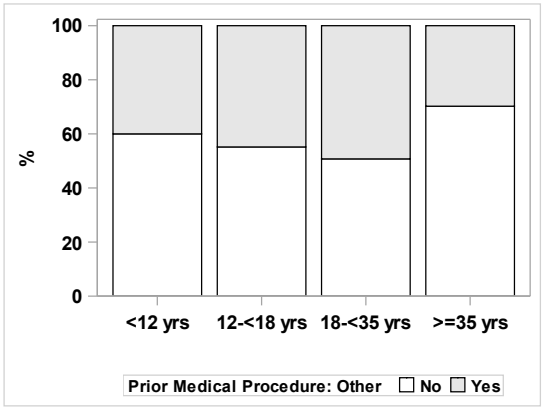


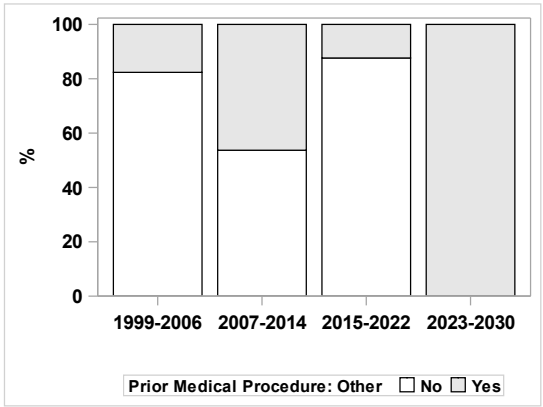
[1] N = Recipients with data
[2] Total = Recipients of the given age group or receiving first transplant in the given era

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

	Age Group (p=<0.001)											
	<12 yrs (N[1]=10, Total [2]=69)			12-<18 yrs (N=29, Total=118)			18-<35 yrs (N=134, Total=335)			>=35 yrs (N=393, Total=798)		
Prior Medical Procedure: Other	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	6	60.0	8.7	16	55.2	13.6	68	50.7	20.3	276	70.2	34.6
Yes	4	40.0	5.8	13	44.8	11.0	66	49.3	19.7	117	29.8	14.7
Missing	59	N/A	85.5	89	N/A	75.4	201	N/A	60.0	405	N/A	50.8

	Era (p=<0.001)											
	Era 1 1999-2006 (N=17, Total=130)			Era 2 2007-2014 (N=378, Total=671)			Era 3 2015-2022 (N=170, Total=516)			Era 4 2023-2030 (N=1, Total=3)		
Prior Medical Procedure: Other	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	14	82.4	10.8	203	53.7	30.3	149	87.6	28.9	0	0.0	0.0
Yes	3	17.6	2.3	175	46.3	26.1	21	12.4	4.1	1	100.0	33.3
Missing	113	N/A	86.9	293	N/A	43.7	346	N/A	67.1	2	N/A	66.7





[1] N = Recipients with data
[2] Total = Recipients of the given age group or receiving first transplant in the given era

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

	Age Group (p=0.12)											
	<12 yrs (N[1]=29, Total [2]=69)			12-<18 yrs (N=55, Total=118)			18-<35 yrs (N=151, Total=335)			>=35 yrs (N=411, Total=798)		
Prior Surgical Procedure: Frey	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	29	100.0	42.0	54	98.2	45.8	146	96.7	43.6	408	99.3	51.1
Yes	0	0.0	0.0	1	1.8	0.8	5	3.3	1.5	3	0.7	0.4
Missing	40	N/A	58.0	63	N/A	53.4	184	N/A	54.9	387	N/A	48.5

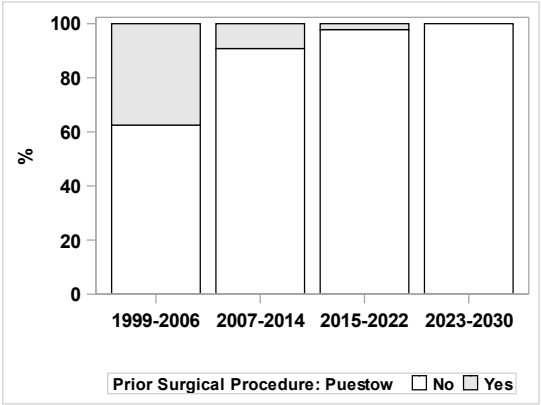
	Era (p=0.30)											
	Era 1 1999-2006 (N=16, Total=130)			Era 2 2007-2014 (N=262, Total=671)			Era 3 2015-2022 (N=365, Total=516)			Era 4 2023-2030 (N=3, Total=3)		
Prior Surgical Procedure: Frey	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	15	93.8	11.5	259	98.9	38.6	360	98.6	69.8	3	100.0	100.0
Yes	1	6.3	0.8	3	1.1	0.4	5	1.4	1.0	0	0.0	0.0
Missing	114	N/A	87.7	409	N/A	61.0	151	N/A	29.3	0	N/A	0.0

[1] N = Recipients with data
[2] Total = Recipients of the given age group or receiving first transplant in the given era

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

	Age Group (p=0.60)											
	<12 yrs (N[1]=31, Total [2]=69)			12-<18 yrs (N=57, Total=118)			18-<35 yrs (N=157, Total=335)			>=35 yrs (N=419, Total=798)		
Prior Surgical Procedure: Puestow	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	29	93.5	42.0	52	91.2	44.1	145	92.4	43.3	396	94.5	49.6
Yes	2	6.5	2.9	5	8.8	4.2	12	7.6	3.6	23	5.5	2.9
Missing	38	N/A	55.1	61	N/A	51.7	178	N/A	53.1	379	N/A	47.5

	Era (p=<0.001)											
	Era 1 1999-2006 (N=24, Total=130)			Era 2 2007-2014 (N=272, Total=671)			Era 3 2015-2022 (N=365, Total=516)			Era 4 2023-2030 (N=3, Total=3)		
Prior Surgical Procedure: Puestow	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	15	62.5	11.5	247	90.8	36.8	357	97.8	69.2	3	100.0	100.0
Yes	9	37.5	6.9	25	9.2	3.7	8	2.2	1.6	0	0.0	0.0
Missing	106	N/A	81.5	399	N/A	59.5	151	N/A	29.3	0	N/A	0.0



[1] N = Recipients with data
[2] Total = Recipients of the given age group or receiving first transplant in the given era

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

	Age Group (p=NS)											
	<12 yrs (N[1]=7, Total [2]=69)			12-<18 yrs (N=25, Total=118)			18-<35 yrs (N=101, Total=335)			>=35 yrs (N=331, Total=798)		
Prior Surgical Procedure: Traveral	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	7	100.0	10.1	25	100.0	21.2	101	100.0	30.1	331	100.0	41.5
Missing	62	N/A	89.9	93	N/A	78.8	234	N/A	69.9	467	N/A	58.5

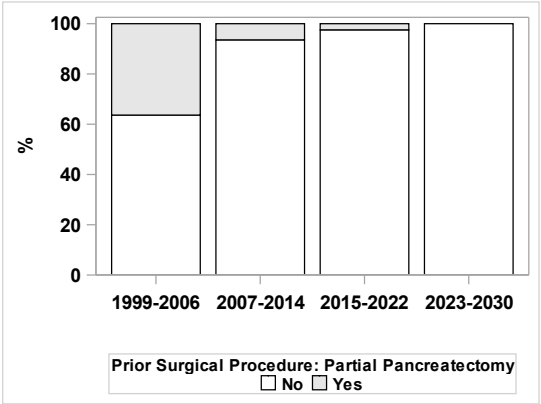
	Era (p=NS)											
	Era 1 1999-2006 (N=15, Total=130)			Era 2 2007-2014 (N=259, Total=671)			Era 3 2015-2022 (N=187, Total=516)			Era 4 2023-2030 (N=3, Total=3)		
Prior Surgical Procedure: Traveral	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	15	100.0	11.5	259	100.0	38.6	187	100.0	36.2	3	100.0	100.0
Missing	115	N/A	88.5	412	N/A	61.4	329	N/A	63.8	0	N/A	0.0

[1] N = Recipients with data
[2] Total = Recipients of the given age group or receiving first transplant in the given era

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

	Age Group (p=0.46)											
	<12 yrs (N[1]=29, Total [2]=69)			12-<18 yrs (N=55, Total=118)			18-<35 yrs (N=154, Total=335)			>=35 yrs (N=419, Total=798)		
Prior Surgical Procedure: Partial Pancreatectomy	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	29	100.0	42.0	54	98.2	45.8	146	94.8	43.6	394	94.0	49.4
Yes	0	0.0	0.0	1	1.8	0.8	8	5.2	2.4	25	6.0	3.1
Missing	40	N/A	58.0	63	N/A	53.4	181	N/A	54.0	379	N/A	47.5

	Era (p=<0.001)											
	Era 1 1999-2006 (N=22, Total=130)			Era 2 2007-2014 (N=264, Total=671)			Era 3 2015-2022 (N=368, Total=516)			Era 4 2023-2030 (N=3, Total=3)		
Prior Surgical Procedure: Partial Pancreatectomy	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	14	63.6	10.8	247	93.6	36.8	359	97.6	69.6	3	100.0	100.0
Yes	8	36.4	6.2	17	6.4	2.5	9	2.4	1.7	0	0.0	0.0
Missing	108	N/A	83.1	407	N/A	60.7	148	N/A	28.7	0	N/A	0.0

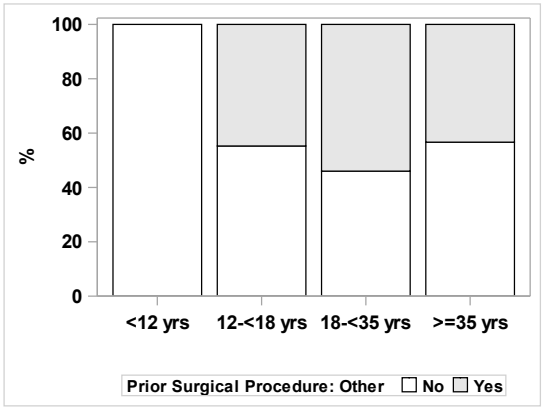


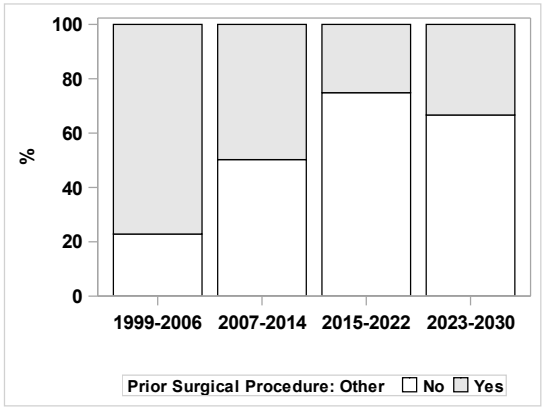
[1] N = Recipients with data
[2] Total = Recipients of the given age group or receiving first transplant in the given era

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

	Age Group (p=<0.01)											
	<12 yrs (N[1]=7, Total [2]=69)			12-<18 yrs (N=38, Total=118)			18-<35 yrs (N=163, Total=335)			>=35 yrs (N=450, Total=798)		
Prior Surgical Procedure: Other	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	7	100.0	10.1	21	55.3	17.8	75	46.0	22.4	255	56.7	32.0
Yes	0	0.0	0.0	17	44.7	14.4	88	54.0	26.3	195	43.3	24.4
Missing	62	N/A	89.9	80	N/A	67.8	172	N/A	51.3	348	N/A	43.6

	Era (p=<0.001)											
	Era 1 1999-2006 (N=70, Total=130)			Era 2 2007-2014 (N=398, Total=671)			Era 3 2015-2022 (N=187, Total=516)			Era 4 2023-2030 (N=3, Total=3)		
Prior Surgical Procedure: Other	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	16	22.9	12.3	200	50.3	29.8	140	74.9	27.1	2	66.7	66.7
Yes	54	77.1	41.5	198	49.7	29.5	47	25.1	9.1	1	33.3	33.3
Missing	60	N/A	46.2	273	N/A	40.7	329	N/A	63.8	0	N/A	0.0





[1] N = Recipients with data
[2] Total = Recipients of the given age group or receiving first transplant in the given era

Exhibit 2-4
Recipient Pancreatectomy Information

	Age Group (p=NS)											
	<12 yrs (N[1]=67, Total [2]=69)			12-<18 yrs (N=118, Total=118)			18-<35 yrs (N=314, Total=335)			>=35 yrs (N=741, Total=798)		
Pancreatectomy Information	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
Yes	67	100.0	97.1	118	100.0	100.0	314	100.0	93.7	741	100.0	92.9
Missing	2	N/A	2.9	0	N/A	0.0	21	N/A	6.3	57	N/A	7.1

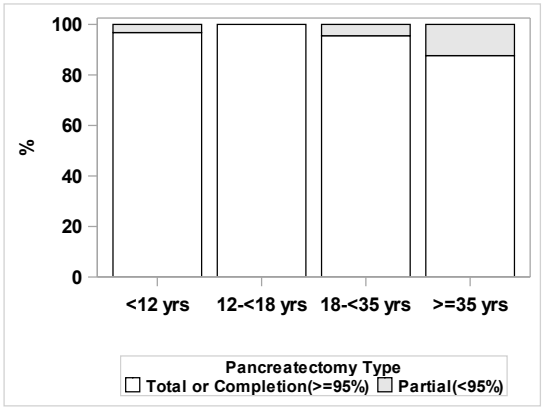
	Era (p=NS)											
	Era 1 1999-2006 (N=129, Total=130)			Era 2 2007-2014 (N=652, Total=671)			Era 3 2015-2022 (N=456, Total=516)			Era 4 2023-2030 (N=3, Total=3)		
Pancreatectomy Information	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
Yes	129	100.0	99.2	652	100.0	97.2	456	100.0	88.4	3	100.0	100.0
Missing	1	N/A	0.8	19	N/A	2.8	60	N/A	11.6	0	N/A	0.0

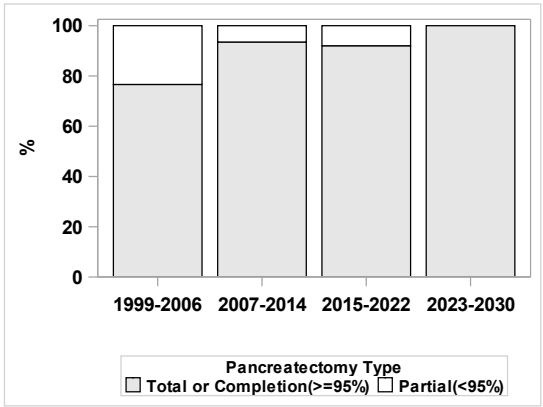
[1] N = Recipients with data
[2] Total = Recipients of the given age group or receiving first transplant in the given era

Exhibit 2-4 (continued)
Recipient Pancreatectomy Information

	Age Group (p=<0.001)											
	<12 yrs (N[1]=62, Total [2]=69)			12-<18 yrs (N=114, Total=118)			18-<35 yrs (N=312, Total=335)			>=35 yrs (N=737, Total=798)		
Pancreatectomy Type	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
Partial(<95%)	2	3.2	2.9	0	0.0	0.0	14	4.5	4.2	91	12.3	11.4
Total or Completion(>=95%)	60	96.8	87.0	114	100.0	96.6	298	95.5	89.0	646	87.7	81.0
Missing	7	N/A	10.1	4	N/A	3.4	23	N/A	6.9	61	N/A	7.6

	Era (p=<0.001)											
	Era 1 1999-2006 (N=124, Total=130)			Era 2 2007-2014 (N=647, Total=671)			Era 3 2015-2022 (N=451, Total=516)			Era 4 2023-2030 (N=3, Total=3)		
Pancreatectomy Type	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
Partial(<95%)	29	23.4	22.3	42	6.5	6.3	36	8.0	7.0	0	0.0	0.0
Total or Completion(>=95%)	95	76.6	73.1	605	93.5	90.2	415	92.0	80.4	3	100.0	100.0
Missing	6	N/A	4.6	24	N/A	3.6	65	N/A	12.6	0	N/A	0.0



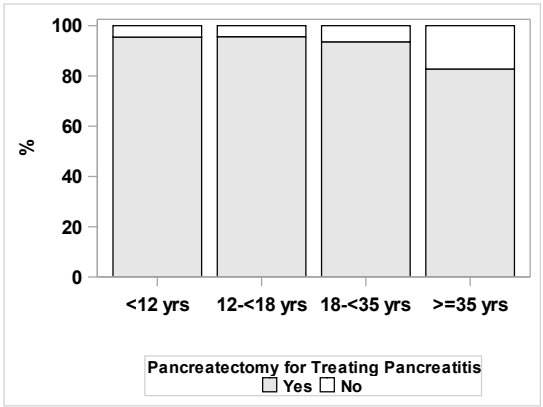


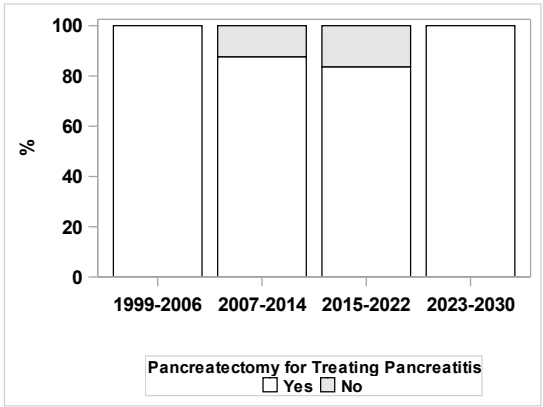
[1] N = Recipients with data
[2] Total = Recipients of the given age group or receiving first transplant in the given era

Exhibit 2-4 (continued)
Recipient Pancreatectomy Information

	Age Group (p=<0.001)											
	<12 yrs (N[1]=66, Total [2]=69)			12-<18 yrs (N=114, Total=118)			18-<35 yrs (N=311, Total=335)			>=35 yrs (N=714, Total=798)		
Pancreatectomy for Treating Pancreatitis	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	3	4.5	4.3	5	4.4	4.2	20	6.4	6.0	123	17.2	15.4
Yes	63	95.5	91.3	109	95.6	92.4	291	93.6	86.9	591	82.8	74.1
Missing	3	N/A	4.3	4	N/A	3.4	24	N/A	7.2	84	N/A	10.5

	Era (p=<0.001)											
	Era 1 1999-2006 (N=123, Total=130)			Era 2 2007-2014 (N=639, Total=671)			Era 3 2015-2022 (N=440, Total=516)			Era 4 2023-2030 (N=3, Total=3)		
Pancreatectomy for Treating Pancreatitis	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	0	0.0	0.0	79	12.4	11.8	72	16.4	14.0	0	0.0	0.0
Yes	123	100.0	94.6	560	87.6	83.5	368	83.6	71.3	3	100.0	100.0
Missing	7	N/A	5.4	32	N/A	4.8	76	N/A	14.7	0	N/A	0.0



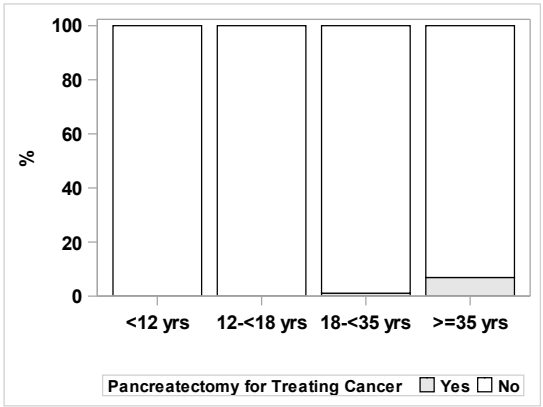


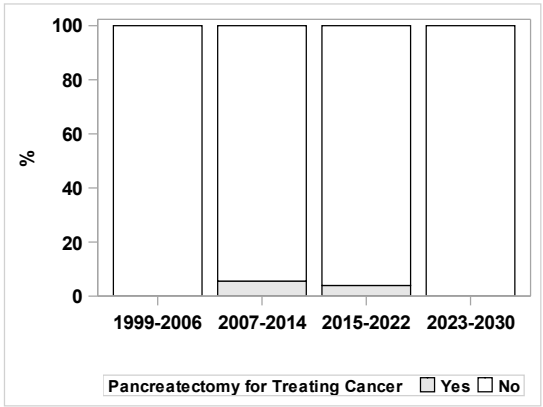
[1] N = Recipients with data
[2] Total = Recipients of the given age group or receiving first transplant in the given era

Exhibit 2-4 (continued)
Recipient Pancreatectomy Information

	Age Group (p=<0.001)											
	<12 yrs (N[1]=62, Total [2]=69)			12-<18 yrs (N=100, Total=118)			18-<35 yrs (N=274, Total=335)			>=35 yrs (N=653, Total=798)		
Pancreatectomy for Treating Cancer	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	62	100.0	89.9	100	100.0	84.7	271	98.9	80.9	608	93.1	76.2
Yes	0	0.0	0.0	0	0.0	0.0	3	1.1	0.9	45	6.9	5.6
Missing	7	N/A	10.1	18	N/A	15.3	61	N/A	18.2	145	N/A	18.2

	Era (p=<0.05)											
	Era 1 1999-2006 (N=114, Total=130)			Era 2 2007-2014 (N=592, Total=671)			Era 3 2015-2022 (N=380, Total=516)			Era 4 2023-2030 (N=3, Total=3)		
Pancreatectomy for Treating Cancer	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	114	100.0	87.7	559	94.4	83.3	365	96.1	70.7	3	100.0	100.0
Yes	0	0.0	0.0	33	5.6	4.9	15	3.9	2.9	0	0.0	0.0
Missing	16	N/A	12.3	79	N/A	11.8	136	N/A	26.4	0	N/A	0.0



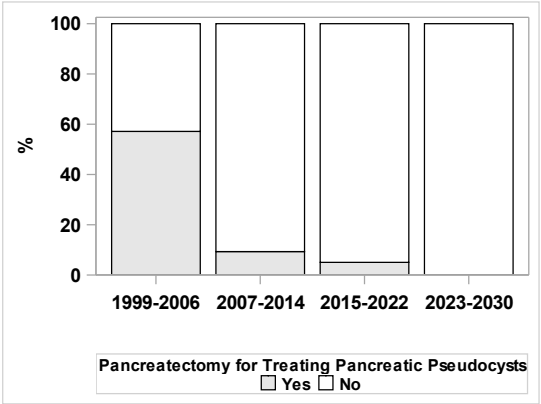


[1] N = Recipients with data
[2] Total = Recipients of the given age group or receiving first transplant in the given era

Exhibit 2-4 (continued)
Recipient Pancreatectomy Information

	Age Group (p=0.36)											
	<12 yrs (N[1]=39, Total [2]=69)			12-<18 yrs (N=65, Total=118)			18-<35 yrs (N=185, Total=335)			>=35 yrs (N=491, Total=798)		
Pancreatectomy for Treating Pancreatic Pseudocysts	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	33	84.6	47.8	61	93.8	51.7	171	92.4	51.0	452	92.1	56.6
Yes	6	15.4	8.7	4	6.2	3.4	14	7.6	4.2	39	7.9	4.9
Missing	30	N/A	43.5	53	N/A	44.9	150	N/A	44.8	307	N/A	38.5

	Era (p=<0.001)											
	Era 1 1999-2006 (N=14, Total=130)			Era 2 2007-2014 (N=386, Total=671)			Era 3 2015-2022 (N=377, Total=516)			Era 4 2023-2030 (N=3, Total=3)		
Pancreatectomy for Treating Pancreatic Pseudocysts	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	6	42.9	4.6	350	90.7	52.2	358	95.0	69.4	3	100.0	100.0
Yes	8	57.1	6.2	36	9.3	5.4	19	5.0	3.7	0	0.0	0.0
Missing	116	N/A	89.2	285	N/A	42.5	139	N/A	26.9	0	N/A	0.0



[1] N = Recipients with data
[2] Total = Recipients of the given age group or receiving first transplant in the given era

Exhibit 2-4 (continued)
Recipient Pancreatectomy Information

	Age Group (p=0.06)											
	<12 yrs (N[1]=61, Total [2]=69)			12-<18 yrs (N=100, Total=118)			18-<35 yrs (N=273, Total=335)			>=35 yrs (N=652, Total=798)		
Pancreatectomy for Treating Pancreatic Cysts	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	61	100.0	88.4	100	100.0	84.7	273	100.0	81.5	640	98.2	80.2
Yes	0	0.0	0.0	0	0.0	0.0	0	0.0	0.0	12	1.8	1.5
Missing	8	N/A	11.6	18	N/A	15.3	62	N/A	18.5	146	N/A	18.3

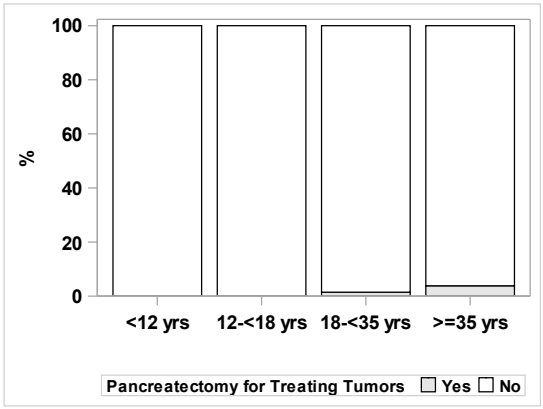
	Era (p=0.12)											
	Era 1 1999-2006 (N=114, Total=130)			Era 2 2007-2014 (N=591, Total=671)			Era 3 2015-2022 (N=378, Total=516)			Era 4 2023-2030 (N=3, Total=3)		
Pancreatectomy for Treating Pancreatic Cysts	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	114	100.0	87.7	587	99.3	87.5	370	97.9	71.7	3	100.0	100.0
Yes	0	0.0	0.0	4	0.7	0.6	8	2.1	1.6	0	0.0	0.0
Missing	16	N/A	12.3	80	N/A	11.9	138	N/A	26.7	0	N/A	0.0

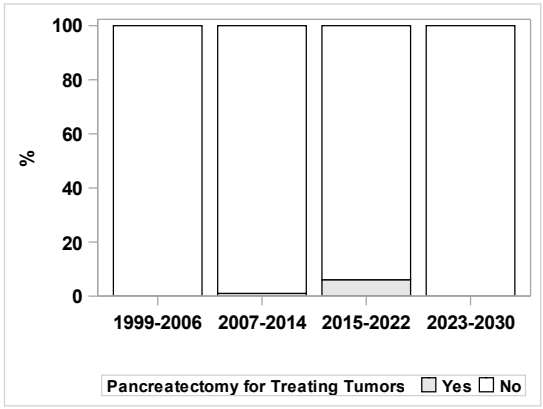
[1] N = Recipients with data
[2] Total = Recipients of the given age group or receiving first transplant in the given era

Exhibit 2-4 (continued)
Recipient Pancreatectomy Information

	Age Group (p=<0.05)											
	<12 yrs (N[1]=61, Total [2]=69)			12-<18 yrs (N=100, Total=118)			18-<35 yrs (N=274, Total=335)			>=35 yrs (N=653, Total=798)		
Pancreatectomy for Treating Tumors	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	61	100.0	88.4	100	100.0	84.7	270	98.5	80.6	628	96.2	78.7
Yes	0	0.0	0.0	0	0.0	0.0	4	1.5	1.2	25	3.8	3.1
Missing	8	N/A	11.6	18	N/A	15.3	61	N/A	18.2	145	N/A	18.2

	Era (p=<0.001)											
	Era 1 1999-2006 (N=114, Total=130)			Era 2 2007-2014 (N=592, Total=671)			Era 3 2015-2022 (N=379, Total=516)			Era 4 2023-2030 (N=3, Total=3)		
Pancreatectomy for Treating Tumors	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	114	100.0	87.7	586	99.0	87.3	356	93.9	69.0	3	100.0	100.0
Yes	0	0.0	0.0	6	1.0	0.9	23	6.1	4.5	0	0.0	0.0
Missing	16	N/A	12.3	79	N/A	11.8	137	N/A	26.6	0	N/A	0.0



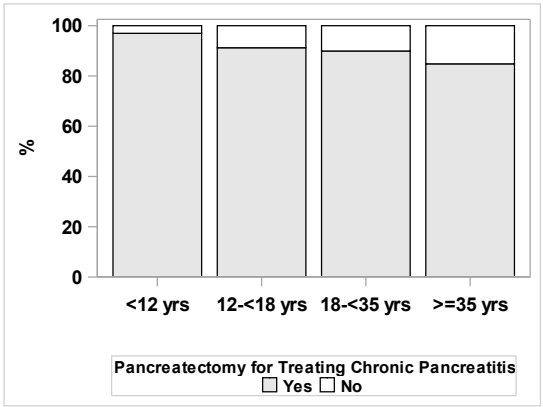


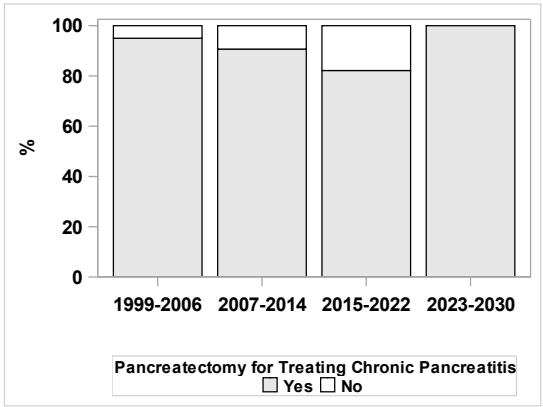
[1] N = Recipients with data
[2] Total = Recipients of the given age group or receiving first transplant in the given era

Exhibit 2-4 (continued)
Recipient Pancreatectomy Information

	Age Group (p=<0.01)											
	<12 yrs (N[1]=66, Total [2]=69)			12-<18 yrs (N=114, Total=118)			18-<35 yrs (N=278, Total=335)			>=35 yrs (N=639, Total=798)		
Pancreatectomy for Treating Chronic Pancreatitis	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	2	3.0	2.9	10	8.8	8.5	28	10.1	8.4	97	15.2	12.2
Yes	64	97.0	92.8	104	91.2	88.1	250	89.9	74.6	542	84.8	67.9
Missing	3	N/A	4.3	4	N/A	3.4	57	N/A	17.0	159	N/A	19.9

	Era (p=<0.001)											
	Era 1 1999-2006 (N=60, Total=130)			Era 2 2007-2014 (N=591, Total=671)			Era 3 2015-2022 (N=443, Total=516)			Era 4 2023-2030 (N=3, Total=3)		
Pancreatectomy for Treating Chronic Pancreatitis	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	3	5.0	2.3	55	9.3	8.2	79	17.8	15.3	0	0.0	0.0
Yes	57	95.0	43.8	536	90.7	79.9	364	82.2	70.5	3	100.0	100.0
Missing	70	N/A	53.8	80	N/A	11.9	73	N/A	14.1	0	N/A	0.0



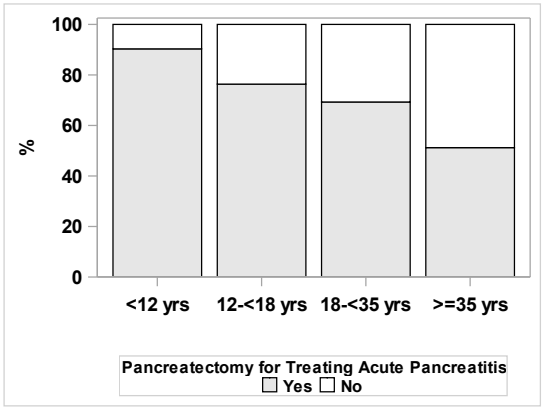


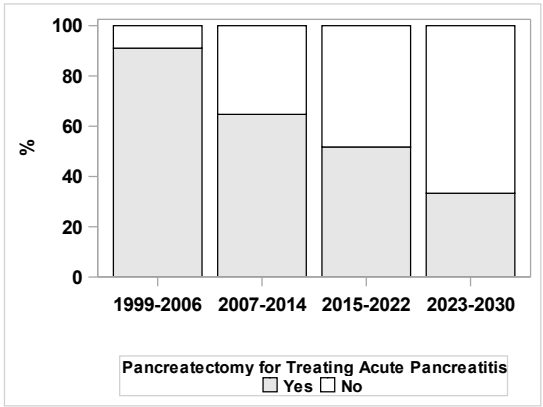
[1] N = Recipients with data
[2] Total = Recipients of the given age group or receiving first transplant in the given era

Exhibit 2-4 (continued)
Recipient Pancreatectomy Information

	Age Group (p=<0.001)											
	<12 yrs (N[1]=62, Total [2]=69)			12-<18 yrs (N=110, Total=118)			18-<35 yrs (N=267, Total=335)			>=35 yrs (N=615, Total=798)		
Pancreatectomy for Treating Acute Pancreatitis	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	6	9.7	8.7	26	23.6	22.0	82	30.7	24.5	300	48.8	37.6
Yes	56	90.3	81.2	84	76.4	71.2	185	69.3	55.2	315	51.2	39.5
Missing	7	N/A	10.1	8	N/A	6.8	68	N/A	20.3	183	N/A	22.9

	Era (p=<0.001)											
	Era 1 1999-2006 (N=56, Total=130)			Era 2 2007-2014 (N=564, Total=671)			Era 3 2015-2022 (N=431, Total=516)			Era 4 2023-2030 (N=3, Total=3)		
Pancreatectomy for Treating Acute Pancreatitis	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	5	8.9	3.8	199	35.3	29.7	208	48.3	40.3	2	66.7	66.7
Yes	51	91.1	39.2	365	64.7	54.4	223	51.7	43.2	1	33.3	33.3
Missing	74	N/A	56.9	107	N/A	15.9	85	N/A	16.5	0	N/A	0.0





[1] N = Recipients with data
[2] Total = Recipients of the given age group or receiving first transplant in the given era

Exhibit 2-4 (continued)
Recipient Pancreatectomy Information

	Age Group (p=0.16)											
	<12 yrs (N[1]=61, Total [2]=69)			12-<18 yrs (N=100, Total=118)			18-<35 yrs (N=274, Total=335)			>=35 yrs (N=653, Total=798)		
Pancreatectomy for Treating Trauma	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	61	100.0	88.4	99	99.0	83.9	268	97.8	80.0	649	99.4	81.3
Yes	0	0.0	0.0	1	1.0	0.8	6	2.2	1.8	4	0.6	0.5
Missing	8	N/A	11.6	18	N/A	15.3	61	N/A	18.2	145	N/A	18.2

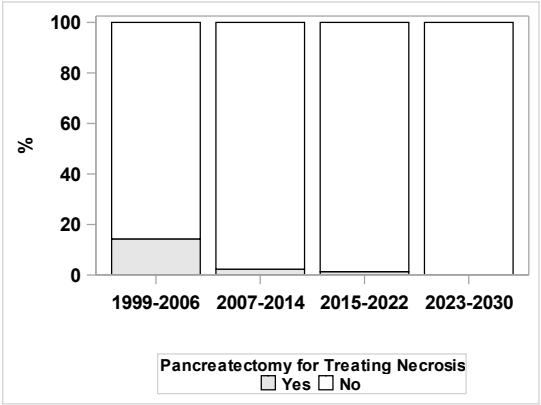
	Era (p=0.08)											
	Era 1 1999-2006 (N=114, Total=130)			Era 2 2007-2014 (N=592, Total=671)			Era 3 2015-2022 (N=379, Total=516)			Era 4 2023-2030 (N=3, Total=3)		
Pancreatectomy for Treating Trauma	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	114	100.0	87.7	589	99.5	87.8	371	97.9	71.9	3	100.0	100.0
Yes	0	0.0	0.0	3	0.5	0.4	8	2.1	1.6	0	0.0	0.0
Missing	16	N/A	12.3	79	N/A	11.8	137	N/A	26.6	0	N/A	0.0

[1] N = Recipients with data
[2] Total = Recipients of the given age group or receiving first transplant in the given era

Exhibit 2-4 (continued)
Recipient Pancreatectomy Information

	Age Group (p=0.59)											
	<12 yrs (N[1]=39, Total [2]=69)			12-<18 yrs (N=64, Total=118)			18-<35 yrs (N=186, Total=335)			>=35 yrs (N=493, Total=798)		
Pancreatectomy for Treating Necrosis	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	39	100.0	56.5	63	98.4	53.4	184	98.9	54.9	480	97.4	60.2
Yes	0	0.0	0.0	1	1.6	0.8	2	1.1	0.6	13	2.6	1.6
Missing	30	N/A	43.5	54	N/A	45.8	149	N/A	44.5	305	N/A	38.2

	Era (p=<0.05)											
	Era 1 1999-2006 (N=14, Total=130)			Era 2 2007-2014 (N=388, Total=671)			Era 3 2015-2022 (N=377, Total=516)			Era 4 2023-2030 (N=3, Total=3)		
Pancreatectomy for Treating Necrosis	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	12	85.7	9.2	379	97.7	56.5	372	98.7	72.1	3	100.0	100.0
Yes	2	14.3	1.5	9	2.3	1.3	5	1.3	1.0	0	0.0	0.0
Missing	116	N/A	89.2	283	N/A	42.2	139	N/A	26.9	0	N/A	0.0



[1] N = Recipients with data
[2] Total = Recipients of the given age group or receiving first transplant in the given era

Exhibit 2-4 (continued)
Recipient Pancreatectomy Information

	Age Group (p=0.46)											
	<12 yrs (N[1]=61, Total [2]=69)			12-<18 yrs (N=100, Total=118)			18-<35 yrs (N=274, Total=335)			>=35 yrs (N=654, Total=798)		
Pancreatectomy for Treating Infection	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	61	100.0	88.4	100	100.0	84.7	274	100.0	81.8	648	99.1	81.2
Yes	0	0.0	0.0	0	0.0	0.0	0	0.0	0.0	6	0.9	0.8
Missing	8	N/A	11.6	18	N/A	15.3	61	N/A	18.2	144	N/A	18.0

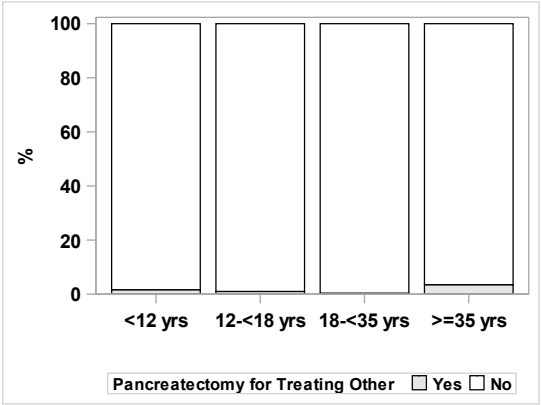
	Era (p=0.17)											
	Era 1 1999-2006 (N=114, Total=130)			Era 2 2007-2014 (N=592, Total=671)			Era 3 2015-2022 (N=380, Total=516)			Era 4 2023-2030 (N=3, Total=3)		
Pancreatectomy for Treating Infection	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	113	99.1	86.9	587	99.2	87.5	380	100.0	73.6	3	100.0	100.0
Yes	1	0.9	0.8	5	0.8	0.7	0	0.0	0.0	0	0.0	0.0
Missing	16	N/A	12.3	79	N/A	11.8	136	N/A	26.4	0	N/A	0.0

[1] N = Recipients with data
[2] Total = Recipients of the given age group or receiving first transplant in the given era

Exhibit 2-4 (continued)
Recipient Pancreatectomy Information

	Age Group (p=<0.05)											
	<12 yrs (N[1]=61, Total [2]=69)			12-<18 yrs (N=99, Total=118)			18-<35 yrs (N=273, Total=335)			>=35 yrs (N=659, Total=798)		
Pancreatectomy for Treating Other	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	60	98.4	87.0	98	99.0	83.1	272	99.6	81.2	636	96.5	79.7
Yes	1	1.6	1.4	1	1.0	0.8	1	0.4	0.3	23	3.5	2.9
Missing	8	N/A	11.6	19	N/A	16.1	62	N/A	18.5	139	N/A	17.4

	Era (p=0.30)											
	Era 1 1999-2006 (N=119, Total=130)			Era 2 2007-2014 (N=596, Total=671)			Era 3 2015-2022 (N=374, Total=516)			Era 4 2023-2030 (N=3, Total=3)		
Pancreatectomy for Treating Other	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	114	95.8	87.7	581	97.5	86.6	368	98.4	71.3	3	100.0	100.0
Yes	5	4.2	3.8	15	2.5	2.2	6	1.6	1.2	0	0.0	0.0
Missing	11	N/A	8.5	75	N/A	11.2	142	N/A	27.5	0	N/A	0.0



[1] N = Recipients with data
[2] Total = Recipients of the given age group or receiving first transplant in the given era

Exhibit 2-4 (continued)
Recipient Pancreatectomy Information

	Age Group												
	<12 years			12 - <18 years			18 - <35 years			>=35 years			
	N	Mean	STE	N	Mean	STE	N	Mean	STE	N	Mean	STE	p
Pancreatitis Duration (yrs)	33	4.2	0.5	65	6.3	0.6	189	7	0.5	385	6.6	0.3	0.111

	Era												
	Era 1 1999-2006			Era 2 2007-2014			Era 3 2015-2022			Era 4 2023-2030			
	N	Mean	STE	N	Mean	STE	N	Mean	STE	N	Mean	STE	p
Pancreatitis Duration (yrs)	99	7.2	0.6	460	6.3	0.3	110	7.2	0.7	3	2.3	1.3	0.217

[1] N = Recipients with data
[2] Total = Recipients of the given age group or receiving first transplant in the given era

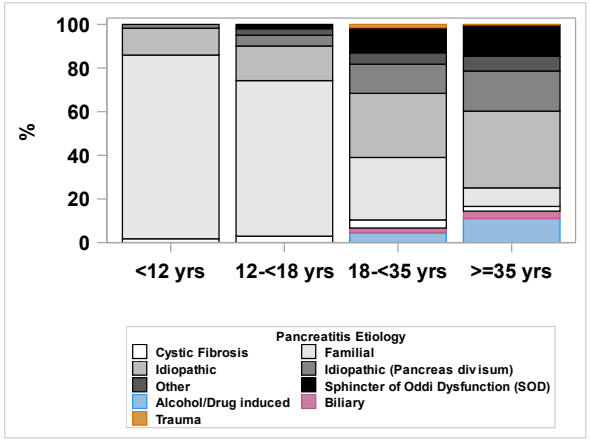
Exhibit 2-4 (continued)
Recipient Pancreatectomy Information

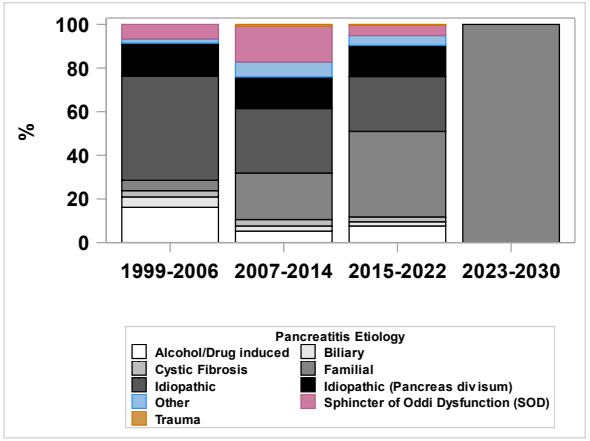
	Age Group (p=<0.001)											
	<12 yrs (N[1]=57, Total [2]=69)			12-<18 yrs (N=101, Total=118)			18-<35 yrs (N=269, Total=335)			>=35 yrs (N=506, Total=798)		
Pancreatitis Etiology	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
Alcohol/Drug induced	0	0.0	0.0	0	0.0	0.0	12	4.5	3.6	56	11.1	7.0
Biliary	0	0.0	0.0	0	0.0	0.0	6	2.2	1.8	17	3.4	2.1
Cystic Fibrosis	1	1.8	1.4	3	3.0	2.5	10	3.7	3.0	11	2.2	1.4
Familial	48	84.2	69.6	72	71.3	61.0	77	28.6	23.0	43	8.5	5.4
Idiopathic	7	12.3	10.1	16	15.8	13.6	79	29.4	23.6	178	35.2	22.3
Idiopathic (Pancreas divisum)	1	1.8	1.4	5	5.0	4.2	36	13.4	10.7	93	18.4	11.7
Sphincter of Oddi Dysfunction (SOD)	0	0.0	0.0	2	2.0	1.7	31	11.5	9.3	73	14.4	9.1
Trauma	0	0.0	0.0	0	0.0	0.0	4	1.5	1.2	1	0.2	0.1
Other	0	0.0	0.0	3	3.0	2.5	14	5.2	4.2	34	6.7	4.3
Missing	12	N/A	17.4	17	N/A	14.4	66	N/A	19.7	292	N/A	36.6

[1] N = Recipients with data
[2] Total = Recipients of the given age group or receiving first transplant in the given era

Exhibit 2-4 (continued)
Recipient Pancreatectomy Information

	Era (p=<0.001)											
	Era 1 1999-2006 (N=105, Total=130)			Era 2 2007-2014 (N=511, Total=671)			Era 3 2015-2022 (N=314, Total=516)			Era 4 2023-2030 (N=3, Total=3)		
Pancreatitis Etiology	n	% of N	% of Total	n	% of N	% of Total	n	% of N	% of Total	n	% of N	% of Total
Alcohol/Drug induced	17	16.2	13.1	27	5.3	4.0	24	7.6	4.7	0	0.0	0.0
Biliary	5	4.8	3.8	12	2.3	1.8	6	1.9	1.2	0	0.0	0.0
Cystic Fibrosis	3	2.9	2.3	15	2.9	2.2	7	2.2	1.4	0	0.0	0.0
Familial	5	4.8	3.8	109	21.3	16.2	123	39.2	23.8	3	100.0	100.0
Idiopathic	50	47.6	38.5	151	29.5	22.5	79	25.2	15.3	0	0.0	0.0
Idiopathic (Pancreas divisum)	16	15.2	12.3	74	14.5	11.0	45	14.3	8.7	0	0.0	0.0
Sphincter of Oddi Dysfunction (SOD)	7	6.7	5.4	84	16.4	12.5	15	4.8	2.9	0	0.0	0.0
Trauma	0	0.0	0.0	4	0.8	0.6	1	0.3	0.2	0	0.0	0.0
Other	2	1.9	1.5	35	6.8	5.2	14	4.5	2.7	0	0.0	0.0
Missing	25	N/A	19.2	160	N/A	23.8	202	N/A	39.1	0	N/A	0.0





[1] N = Recipients with data
[2] Total = Recipients of the given age group or receiving first transplant in the given era

Exhibit 2-5
Recipient Laboratory Values at First Infusion

	Age Group												
	<12 years			12 - <18 years			18 - <35 years			>=35 years			
	N	Mean	STE	N	Mean	STE	N	Mean	STE	N	Mean	STE	p
HbA1C (%)	58	5.3	0.1	88	5.3	0.1	235	5.4	0.1	564	5.7	0	<0.001
Basal C-Peptide (ng/mL)	50	1.4	0.2	84	2	0.1	230	2.1	0.1	542	2.2	0.1	0.002
Fasting Blood Glucose (mg/dL)	51	88.7	1.3	86	89.2	1.2	209	94.3	1.3	466	102.4	1.5	<0.001
ALT (U/L)	52	28.6	3.5	84	38.6	4.9	246	37.5	2.2	636	37.2	1.6	0.465
AST (U/L)	51	32.1	1.6	81	34.6	3.3	244	33.8	1.6	633	35.1	1.5	0.904
Alkaline Phosphatase (U/L)	52	231.6	10	84	149.7	8.6	239	84.4	2.3	612	99.1	2.8	<0.001
Total Bilirubin (mg/dL)	52	0.3	0	82	0.5	0	242	0.5	0	619	0.6	0	0.033
Total Cholesterol (mg/dL)	1	134	.	7	135.9	8.7	38	162.4	6.6	102	180.4	4.4	0.011
HDL (mg/dL)	1	38	.	6	49.8	6.7	37	46	2.7	99	47.8	1.6	0.842
LDL (mg/dL)	1	90	.	6	56.5	11.2	36	90.6	6.2	85	107.1	4.2	0.005
Triglycerides (mg/dL)	1	28	.	7	83.3	16.2	38	133.9	14	112	120.5	6.9	0.224
Serum Creatinine (mg/dL)	27	0.4	0	56	0.7	0.1	179	0.8	0	497	0.8	0	<0.001
eGFR-CKD (mL/min/1.73m ^{2})	27	175.7	5.5	56	136.6	3.4	179	112.4	1.6	497	94.4	0.8	<0.001

Significant differences by age group and era are displayed in the following box-and-whisker plots.

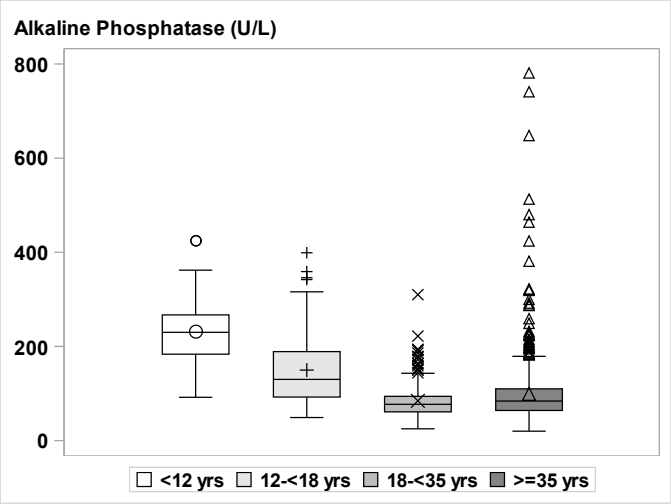
Exhibit 2-5
Recipient Laboratory Values at First Infusion

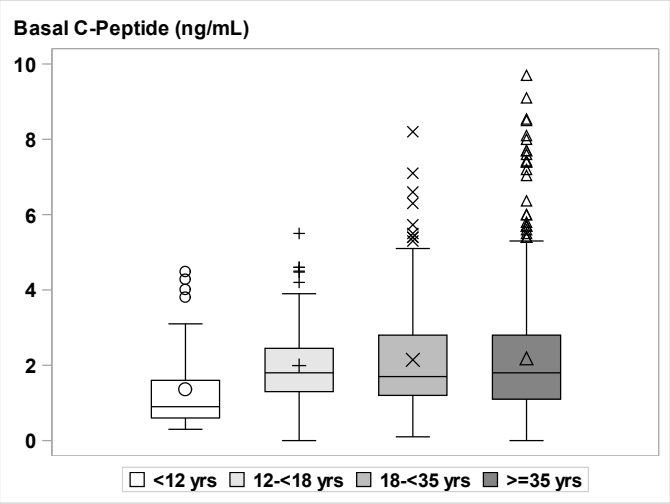
	Era												
	Era 1 1999-2006			Era 2 2007-2014			Era 3 2015-2022			Era 4 2023-2030			
	N	Mean	STE	N	Mean	STE	N	Mean	STE	N	Mean	STE	p
HbA1C (%)	29	5.2	0.1	533	5.5	0	381	5.6	0	2	5.3	0.2	0.008
Basal C-Peptide (ng/mL)	21	2.3	0.4	539	2	0.1	344	2.2	0.1	2	2.5	2	0.128
Fasting Blood Glucose (mg/dL)	15	93.3	1.9	442	95.4	1.3	352	101.8	1.4	3	75.3	3.4	0.003
ALT (U/L)	50	48.1	7.3	586	36.7	1.7	379	36	1.8	3	21.7	2.3	0.193
AST (U/L)	48	39.3	4.5	586	34.7	1.3	373	33.8	1.9	2	29.5	12.5	0.751
Alkaline Phosphatase (U/L)	49	108.7	7.8	580	107.2	2.8	355	105.6	4.3	3	168.3	70.4	0.516
Total Bilirubin (mg/dL)	48	0.4	0	583	0.5	0	362	0.6	0	2	0.3	0	0.472
Total Cholesterol (mg/dL)	2	193	50	49	178.2	6.2	97	170.5	4.5	0	.	.	0.497
HDL (mg/dL)	2	44.5	9.5	47	45.9	2.7	94	48.1	1.5	0	.	.	0.714
LDL (mg/dL)	0	.	.	41	102.3	5.9	87	98.8	4.3	0	.	.	0.633
Triglycerides (mg/dL)	4	131	59.7	57	136.7	12.3	97	112.2	6.1	0	.	.	0.145
Serum Creatinine (mg/dL)	17	0.8	0.1	335	0.8	0	404	0.8	0	3	0.4	0.1	0.311
eGFR-CKD (mL/min/1.73m ^{2})	17	98	3.7	335	99.5	1.2	404	108.8	1.5	3	167.6	40.2	<0.001

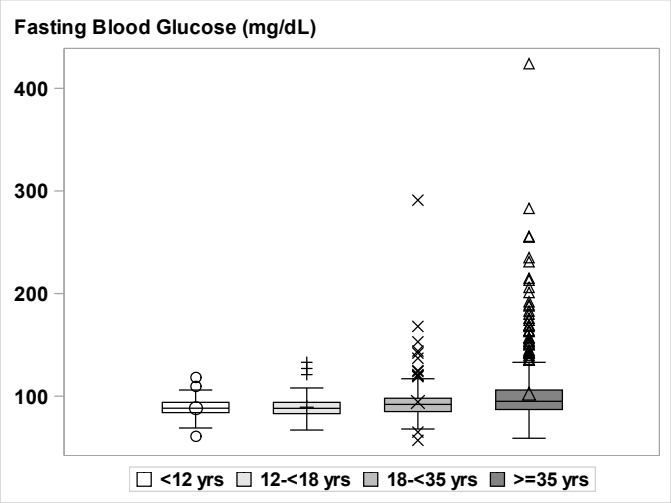
Significant differences by age group and era are displayed in the following box-and-whisker plots.

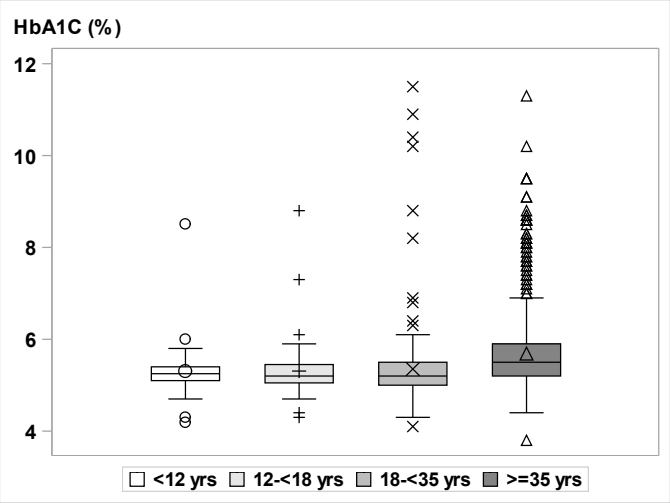
Exhibit 2-5 (continued)
Recipient Laboratory Values at First Infusion

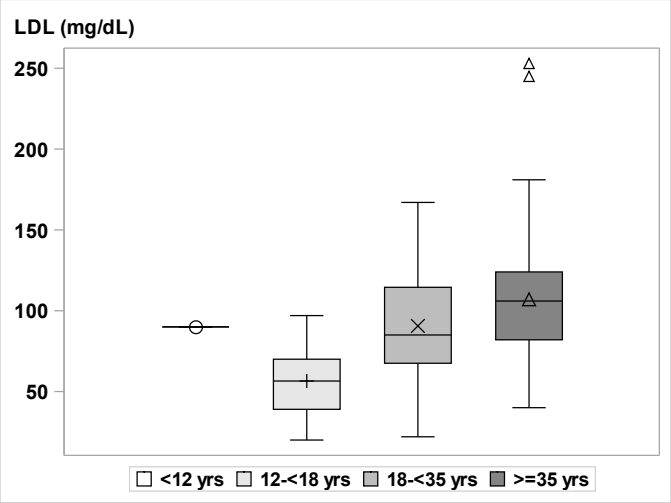
Significant trends in patient characteristics from table above by Age Group











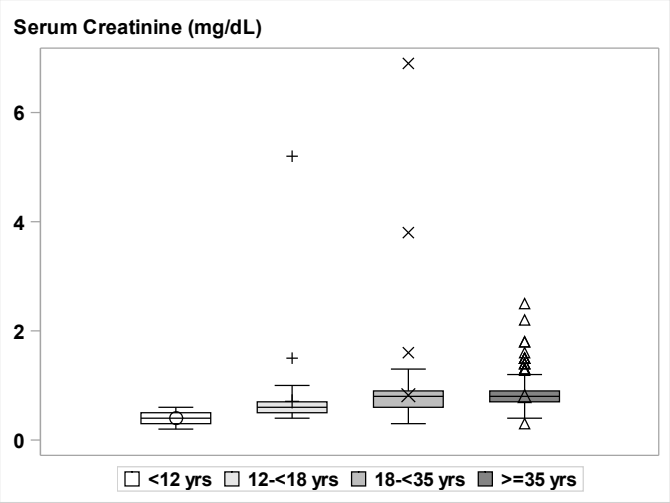
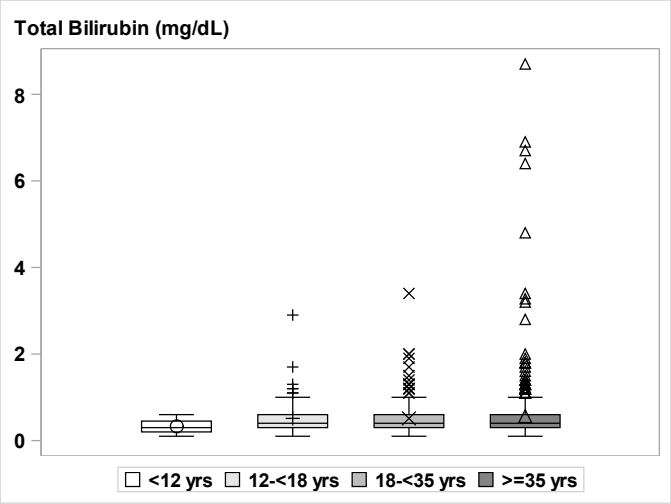
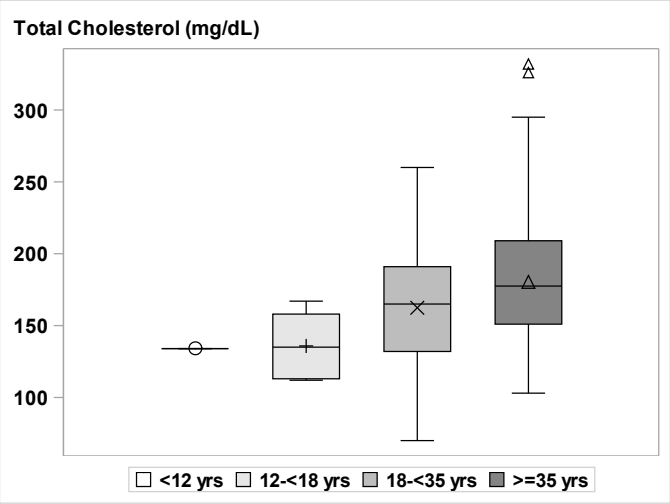


Exhibit 2-5 (continued)
Recipient Laboratory Values at First Infusion

Significant trends in patient characteristics from table above by Age Group





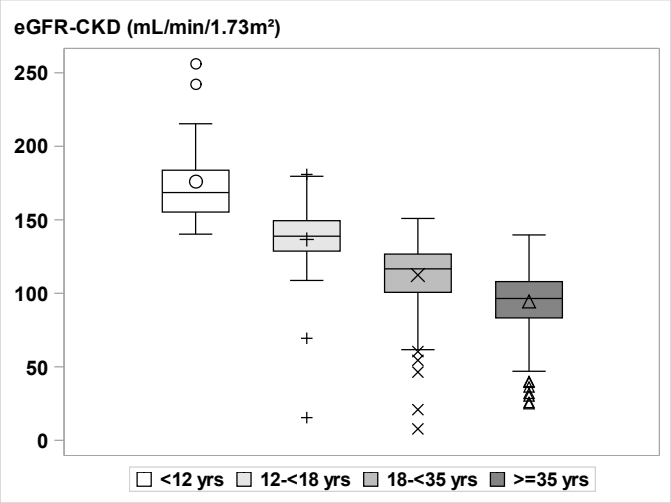
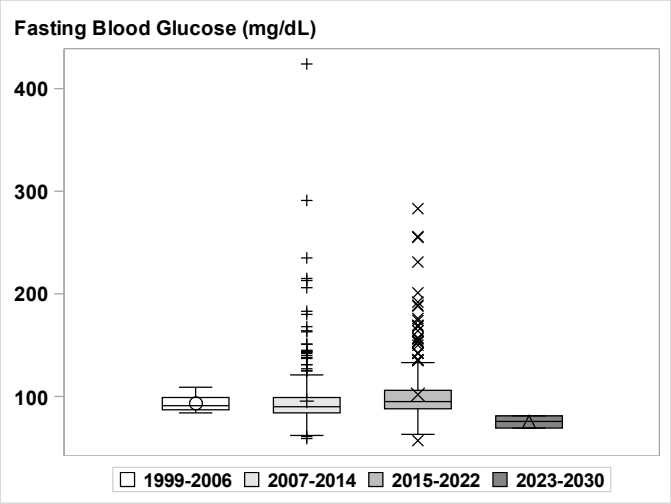
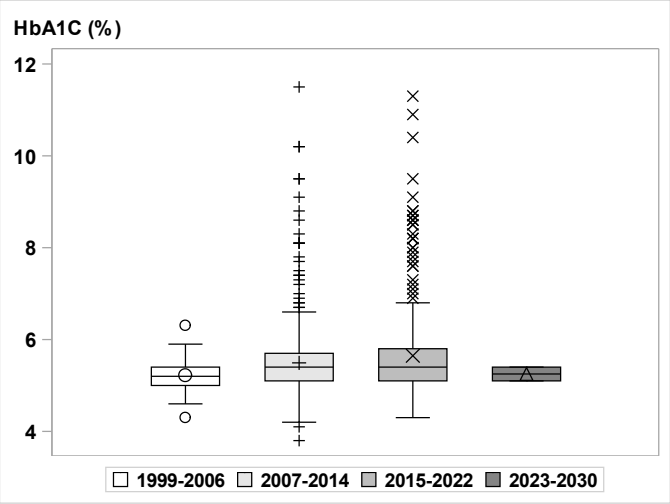
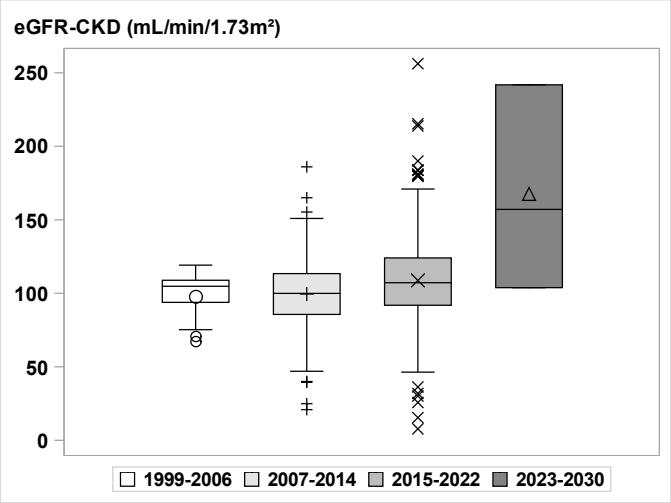


Exhibit 2-5 (continued)
Recipient Laboratory Values at First Infusion

Significant trends in patient characteristics from table above by Era







Chapter 3
Pancreas Procurement, Islet Processing, and Infusion Characteristics

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Introduction

Data elements in this Chapter that were too sparsely reported to allow any meaningful tabulation of results were intentionally omitted.

Cold ischemia time is generally quite short, averaging anywhere from 1.1±0.2 (1999-2006) to 1.4±0.1 (2014-2022) hours across prior eras (Exhibit 3-2).

Total cell volume increased significantly with increasing age. Children <12 years old had significantly lower total IEQs, but higher IEQs/kg and higher percentage of Embedded islets than older age groups (Exhibit 3-3).

Donor weight and BMI were positively correlated with packed cell volume and total IEQs. Donor height, weight, and BMI were negatively correlated with IEQs/kg. Cold ischemia time was negatively correlated with total IEQs and IEQs/kg (Exhibit 3-4).

Exhibit 3-1A
Islet Processing Summary

	Age Group (p=<0.001)											
	<12 yrs (N[1]=31, Total [2]=71)			12-<18 yrs (N[1]=52, Total [2]=119)			18-<35 yrs (N[1]=132, Total [2]=336)			>=35 yrs (N[1]=348, Total [2]=803)		
Gradient type	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
Continuous	0	0.0	0.0	2	3.8	1.7	24	18.2	7.1	107	30.7	13.3
Discontinuous	1	3.2	1.4	0	0.0	0.0	6	4.5	1.8	13	3.7	1.6
None	30	96.8	42.3	50	96.2	42.0	102	77.3	30.4	228	65.5	28.4
Missing	40	N/A	56.3	67	N/A	56.3	204	N/A	60.7	455	N/A	56.7

	Era (p=<0.001)											
	Era 1 1999-2006 (N=40, Total=134)			Era 2 2007-2014 (N=208, Total=676)			Era 3 2015-2022 (N=314, Total=516)			Era 4 2023-2030 (N=1, Total=3)		
Gradient type	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
Continuous	2	5.0	1.5	77	37.0	11.4	54	17.2	10.5	0	0.0	0.0
Discontinuous	2	5.0	1.5	15	7.2	2.2	3	1.0	0.6	0	0.0	0.0
None	36	90.0	26.9	116	55.8	17.2	257	81.8	49.8	1	100.0	33.3
Missing	94	N/A	70.1	468	N/A	69.2	202	N/A	39.1	2	N/A	66.7

[1] N = Recipients with data
[2] Total = Recipients of the given transplant type or receiving first transplant in the given era

Exhibit 3-1A
Islet Processing Summary

	Age Group (p=0.21)											
	<12 yrs (N[1]=11, Total [2]=71)			12-<18 yrs (N[1]=27, Total [2]=119)			18-<35 yrs (N[1]=94, Total [2]=336)			>=35 yrs (N[1]=329, Total [2]=803)		
Incubated in preservation solution	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	11	100.0	15.5	26	96.3	21.8	81	86.2	24.1	277	84.2	34.5
Yes	0	0.0	0.0	1	3.7	0.8	13	13.8	3.9	52	15.8	6.5
Missing	60	N/A	84.5	92	N/A	77.3	242	N/A	72.0	474	N/A	59.0

	Era (p=0.33)											
	Era 1 1999-2006 (N=16, Total=134)			Era 2 2007-2014 (N=238, Total=676)			Era 3 2015-2022 (N=204, Total=516)			Era 4 2023-2030 (N=3, Total=3)		
Incubated in preservation solution	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	15	93.8	11.2	197	82.8	29.1	180	88.2	34.9	3	100.0	100.0
Yes	1	6.3	0.7	41	17.2	6.1	24	11.8	4.7	0	0.0	0.0
Missing	118	N/A	88.1	438	N/A	64.8	312	N/A	60.5	0	N/A	0.0

[1] N = Recipients with data
[2] Total = Recipients of the given transplant type or receiving first transplant in the given era

Exhibit 3-1A
Islet Processing Summary

	Age Group (p=0.84)											
	<12 yrs (N[1]=11, Total [2]=71)			12-<18 yrs (N[1]=27, Total [2]=119)			18-<35 yrs (N[1]=88, Total [2]=336)			>=35 yrs (N[1]=314, Total [2]=803)		
Preservation solution used	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	0	0.0	0.0	1	3.7	0.8	2	2.3	0.6	10	3.2	1.2
Yes	11	100.0	15.5	26	96.3	21.8	86	97.7	25.6	304	96.8	37.9
Missing	60	N/A	84.5	92	N/A	77.3	248	N/A	73.8	489	N/A	60.9

	Era (p=<0.05)											
	Era 1 1999-2006 (N=12, Total=134)			Era 2 2007-2014 (N=232, Total=676)			Era 3 2015-2022 (N=193, Total=516)			Era 4 2023-2030 (N=3, Total=3)		
Preservation solution used	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
No	1	8.3	0.7	8	3.4	1.2	3	1.6	0.6	1	33.3	33.3
Yes	11	91.7	8.2	224	96.6	33.1	190	98.4	36.8	2	66.7	66.7
Missing	122	N/A	91.0	444	N/A	65.7	323	N/A	62.6	0	N/A	0.0

[1] N = Recipients with data
[2] Total = Recipients of the given transplant type or receiving first transplant in the given era

Exhibit 3-1A
Islet Processing Summary

	Age Group (p=<0.001)											
	<12 yrs (N[1]=32, Total [2]=71)			12-<18 yrs (N[1]=57, Total [2]=119)			18-<35 yrs (N[1]=148, Total [2]=336)			>=35 yrs (N[1]=379, Total [2]=803)		
Islet purification	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
Density gradient	2	6.3	2.8	4	7.0	3.4	39	26.4	11.6	139	36.7	17.3
None	30	93.8	42.3	50	87.7	42.0	102	68.9	30.4	228	60.2	28.4
Other	0	0.0	0.0	3	5.3	2.5	7	4.7	2.1	12	3.2	1.5
Missing	39	N/A	54.9	62	N/A	52.1	188	N/A	56.0	424	N/A	52.8

	Era (p=<0.001)											
	Era 1 1999-2006 (N=44, Total=134)			Era 2 2007-2014 (N=219, Total=676)			Era 3 2015-2022 (N=352, Total=516)			Era 4 2023-2030 (N=1, Total=3)		
Islet purification	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
Density gradient	4	9.1	3.0	94	42.9	13.9	86	24.4	16.7	0	0.0	0.0
None	36	81.8	26.9	116	53.0	17.2	257	73.0	49.8	1	100.0	33.3
Other	4	9.1	3.0	9	4.1	1.3	9	2.6	1.7	0	0.0	0.0
Missing	90	N/A	67.2	457	N/A	67.6	164	N/A	31.8	2	N/A	66.7

[1] N = Recipients with data
[2] Total = Recipients of the given transplant type or receiving first transplant in the given era

Exhibit 3-1A
Islet Processing Summary

	Age Group (p=0.71)											
	<12 yrs (N[1]=10, Total [2]=71)			12-<18 yrs (N[1]=26, Total [2]=119)			18-<35 yrs (N[1]=94, Total [2]=336)			>=35 yrs (N[1]=306, Total [2]=803)		
Gram stain	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
0	8	80.0	11.3	20	76.9	16.8	80	85.1	23.8	249	81.4	31.0
Gram stain +	2	20.0	2.8	6	23.1	5.0	14	14.9	4.2	57	18.6	7.1
Missing	61	N/A	85.9	93	N/A	78.2	242	N/A	72.0	497	N/A	61.9

	Era (p=0.20)											
	Era 1 1999-2006 (N=12, Total=134)			Era 2 2007-2014 (N=222, Total=676)			Era 3 2015-2022 (N=200, Total=516)			Era 4 2023-2030 (N=2, Total=3)		
Gram stain	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
0	12	100.0	9.0	181	81.5	26.8	163	81.5	31.6	1	50.0	33.3
Gram stain +	0	0.0	0.0	41	18.5	6.1	37	18.5	7.2	1	50.0	33.3
Missing	122	N/A	91.0	454	N/A	67.2	316	N/A	61.2	1	N/A	33.3

[1] N = Recipients with data
[2] Total = Recipients of the given transplant type or receiving first transplant in the given era

Exhibit 3-1B
Final Islet Preparation Microbiology

	Age Group (p=<0.05)											
	<12 yrs (N[1]=10, Total [2]=71)			12-<18 yrs (N[1]=27, Total [2]=119)			18-<35 yrs (N[1]=109, Total [2]=336)			>=35 yrs (N[1]=294, Total [2]=803)		
Aerobic culture	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
Negative	5	50.0	7.0	19	70.4	16.0	84	77.1	25.0	243	82.7	30.3
Positive	5	50.0	7.0	8	29.6	6.7	25	22.9	7.4	51	17.3	6.4
Missing	61	N/A	85.9	92	N/A	77.3	227	N/A	67.6	509	N/A	63.4

	Era (p=0.19)											
	Era 1 1999-2006 (N=36, Total=134)			Era 2 2007-2014 (N=238, Total=676)			Era 3 2015-2022 (N=165, Total=516)			Era 4 2023-2030 (N=1, Total=3)		
Aerobic culture	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
Negative	25	69.4	18.7	197	82.8	29.1	128	77.6	24.8	1	100.0	33.3
Positive	11	30.6	8.2	41	17.2	6.1	37	22.4	7.2	0	0.0	0.0
Missing	98	N/A	73.1	438	N/A	64.8	351	N/A	68.0	2	N/A	66.7

[1] N = Recipients with data
[2] Total = Recipients of the given transplant type or receiving first transplant in the given era

Exhibit 3-1B
Final Islet Preparation Microbiology

	Age Group (p=<0.01)											
	<12 yrs (N[1]=10, Total [2]=71)			12-<18 yrs (N[1]=27, Total [2]=119)			18-<35 yrs (N[1]=108, Total [2]=336)			>=35 yrs (N[1]=297, Total [2]=803)		
Anaerobic culture	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
Negative	5	50.0	7.0	20	74.1	16.8	82	75.9	24.4	253	85.2	31.5
Positive	5	50.0	7.0	7	25.9	5.9	26	24.1	7.7	44	14.8	5.5
Missing	61	N/A	85.9	92	N/A	77.3	228	N/A	67.9	506	N/A	63.0

	Era (p=<0.05)											
	Era 1 1999-2006 (N=34, Total=134)			Era 2 2007-2014 (N=243, Total=676)			Era 3 2015-2022 (N=164, Total=516)			Era 4 2023-2030 (N=1, Total=3)		
Anaerobic culture	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
Negative	31	91.2	23.1	205	84.4	30.3	123	75.0	23.8	1	100.0	33.3
Positive	3	8.8	2.2	38	15.6	5.6	41	25.0	7.9	0	0.0	0.0
Missing	100	N/A	74.6	433	N/A	64.1	352	N/A	68.2	2	N/A	66.7

[1] N = Recipients with data
[2] Total = Recipients of the given transplant type or receiving first transplant in the given era

Exhibit 3-1B
Final Islet Preparation Microbiology

	Age Group (p=0.67)											
	<12 yrs (N[1]=10, Total [2]=71)			12-<18 yrs (N[1]=21, Total [2]=119)			18-<35 yrs (N[1]=85, Total [2]=336)			>=35 yrs (N[1]=244, Total [2]=803)		
Fungal culture	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
Negative	10	100.0	14.1	21	100.0	17.6	82	96.5	24.4	240	98.4	29.9
Positive	0	0.0	0.0	0	0.0	0.0	3	3.5	0.9	4	1.6	0.5
Missing	61	N/A	85.9	98	N/A	82.4	251	N/A	74.7	559	N/A	69.6

	Era (p=0.58)											
	Era 1 1999-2006 (N=12, Total=134)			Era 2 2007-2014 (N=184, Total=676)			Era 3 2015-2022 (N=163, Total=516)			Era 4 2023-2030 (N=1, Total=3)		
Fungal culture	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**	**n**	**% of N**	**% of Total**
Negative	12	100.0	9.0	179	97.3	26.5	161	98.8	31.2	1	100.0	33.3
Positive	0	0.0	0.0	5	2.7	0.7	2	1.2	0.4	0	0.0	0.0
Missing	122	N/A	91.0	492	N/A	72.8	353	N/A	68.4	2	N/A	66.7

[1] N = Recipients with data
[2] Total = Recipients of the given transplant type or receiving first transplant in the given era

Exhibit 3-2
Cold Ischemia Information

	Age Group												
	<12 yrs			12-<18 yrs			18-<35 yrs			>=35 yrs			
	N	Mean	STE	N	Mean	STE	N	Mean	STE	N	Mean	STE	p
Time from admission to pancreatectomy (hrs)	5	20.3	0.8	10	17.5	3.7	35	11.5	3.8	82	20.4	4.1	0.578
Time from pancreatectomy to transplant (hrs)	3	3	1	8	2.2	0.5	34	4.3	1	93	8.9	1.5	0.174
Time from cross clamp to pancreas recovery (hrs)	0	.	.	0	.	.	0	.	.	0	.	.	
Duration of cold ischemia (hrs)	11	1.5	0.5	19	2.5	0.5	64	1.5	0.2	214	1.6	0.1	0.153
Culture time (hrs)	0	.	.	0	.	.	0	.	.	0	.	.	

[1] N = Recipients with data
[2] Total = Recipients of the given transplant type or receiving first transplant in the given era

Exhibit 3-2
Cold Ischemia Information

	Era												
	Era 1 1999-2006			Era 2 2007-2014			Era 3 2015-2022			Era 4 2023-2030			
	N	Mean	STE	N	Mean	STE	N	Mean	STE	N	Mean	STE	p
Time from admission to pancreatectomy (hrs)	9	45.1	8.4	43	11.1	2.8	78	18.211 538	4.1334 281	2	22.15	1.75	0.031
Time from pancreatectomy to transplant (hrs)	8	1	0.2	50	4.2	0.6	78	10.005 128	1.8170 602	2	1.65	0.25	0.030
Time from cross clamp to pancreas recovery (hrs)	0	.	.	0	.	.	0	.	.	0	.	.	
Duration of cold ischemia (hrs)	13	1.1	0.2	157	1.8	0.2	136	1.4419 118	0.1269 705	2	4.75	0.15	0.012
Culture time (hrs)	0	.	.	0	.	.	0	.	.	0	.	.	

[1] N = Recipients with data
[2] Total = Recipients of the given transplant type or receiving first transplant in the given era

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

	Age Group												
	<12 yrs			12-<18 yrs			18-<35 yrs			>=35 yrs			
	N	Mean	STE	N	Mean	STE	N	Mean	STE	N	Mean	STE	p
Total cell volume	28	5.4	0.8	51	8.7	0.9	133	9.9	0.6	276	10.3	0.4	0.002
Total islet particles (final preparation)	66	216.6	14	112	276.6	15.1	297	299.9	10.8	648	274	6.8	0.004
Embedded islets (%)	6	52.5	14.5	16	29.4	5.9	54	29.3	3.1	183	25.4	1.6	0.026
Islet equivalents (1000s)	67	179.4	11.8	114	255.3	15.1	302	275.3	10.5	653	267.4	7.4	0.001
Islet equivalents(1000s)/kg recipient	33	6.9	0.8	52	4.3	0.3	143	3.8	0.2	363	3.8	0.2	<0.001
Total Endotoxin units	11	38.1	22	19	27.2	18.7	60	47.3	10.1	171	36.5	3.9	0.562
Endotoxin units/kg recipient weight	11	0.7	0.4	17	0.5	0.4	58	0.7	0.1	161	0.5	0.1	0.629
Islet viability	9	95	1.8	24	95.4	1	83	94.7	0.6	274	94.3	0.3	0.744
Purity	9	19.1	4.3	16	23.6	3.3	54	25.8	2.7	162	28.6	1.8	0.432

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

	Era												
	Era 1 1999-2006			Era 2 2007-2014			Era 3 2015-2022			Era 4 2023-2030			
	N	Mean	STE	N	Mean	STE	N	Mean	STE	N	Mean	STE	p
Total cell volume	29	10	1.2	228	9.1	0.4	228	10.3	0.5	3	11.3	4.5	0.285
Total islet particles (final preparation)	143	250.3	15.3	586	282.6	7.3	391	280.4	8.4	3	288.8	135.8	0.246
Embedded islets (%)	6	14.8	4.4	110	27.1	2.2	143	27.5	1.9	0	.	.	0.412
Islet equivalents (1000s)	144	209.2	11.8	577	273.3	7.9	412	267.6	9	3	285.5	139.1	0.002
Islet equivalents(1000s)/kg recipient	14	3.1	0.5	195	4.2	0.2	379	4	0.1	3	11.6	7.4	<0.001
Total Endotoxin units	11	31	11.4	121	57.7	6.8	128	20.9	3.5	1	0.6	.	<0.001
Endotoxin units/kg recipient weight	9	0.5	0.2	115	0.8	0.1	122	0.3	0.1	1	0	.	<0.001
Islet viability	5	89.4	5.4	205	93.8	0.4	180	95.4	0.4	0	.	.	<0.001
Purity	8	44.1	13.5	106	27.6	2.3	127	26.1	1.5	0	.	.	0.063

Exhibit 3-4
Correlation of Islet Characteristics with Donor, 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 Endotoxin**	**Endotoxin/kg donor**
Age at Baseline (yrs)	0.0193	-0.0028	-0.0907	0.0405	-0.105	0.0316	-0.0123
	0.671	0.9248	0.1485	0.1764	0.0108	0.614	0.8488
	487	1102	255	1114	588	257	243
Cold ischemic time (hrs)	-0.0387	-0.1017	0.0584	-0.1877	-0.1716	-0.114	-0.062
	0.7417	0.0929	0.4212	0.002	0.0057	0.0987	0.3819
	75	274	192	268	258	211	201
Donor Body Mass Index (kg/m ^{2})	0.2028	0.0823	0.0411	0.2114	-0.1369	0.0793	-0.0442
	0.0006	0.0545	0.5377	0	0.0011	0.229	0.5033
	286	546	227	563	569	232	232
Donor Height	0.1224	-0.015	-0.0534	0.0696	-0.1832	0.0612	-0.0115
	0.0368	0.7249	0.4181	0.0964	0	0.3474	0.8622
	291	555	232	572	569	238	232
Donor Weight (kg)	0.2244	0.0742	0.0572	0.2026	-0.1848	0.0856	-0.0538
	0.0001	0.0761	0.378	0	0	0.1838	0.404
	293	572	240	582	588	243	243
Hours from admission to pancreatectomy	-0.2321	-0.1183	-0.0432	-0.0476	-0.0389	-0.1504	-0.1834
	0.0978	0.2386	0.7304	0.635	0.6979	0.2107	0.1373
	52	101	66	102	102	71	67
Hours from pancreatectomy to transplant	-0.1737	-0.2374	0.1731	-0.2733	-0.2381	-0.2087	-0.1995
	0.1884	0.0134	0.1646	0.004	0.0131	0.0807	0.1055
	59	108	66	109	108	71	67

Chapter 4
Autograft Recipient Medications

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Chapter 5
Graft Function

Introduction

Unlike with allo-islet transplantation, time to first insulin independence is not a measure of engraftment for auto-islet transplantation and has been intentionally omitted.

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. There were significant differences in **insulin independence** following Auto-ITx across the age groups, with the youngest (<12 years old) achieving the highest percentage insulin independent, but durability was consistent across age groups with very little decline observed over the 5 years post auto-ITx transplant (Exhibit 5-1A). Other factors were investigated by age group.

Recipients ≥35 years old (Exhibit 5-1B)

Insulin independence rates were significantly higher in those with Fasting Blood Glucose <100 mg/dL at baseline (p<0.0001) and those with HbA1c <6.5% at baseline (p=0.0014). Female recipients (p<0.0001) and donors (p<0.0001) also showed greatly improved rates of insulin independence.

Islet IEQs for all infusions ≥500,000 (p=0.0010), IEQs infused ≥500,000 (p=0.0032), and IEQs/kg ≥3,000 (p=0.0007) were all associated with higher rates of insulin independence. Islets IEQs/kg recipient <5.15k reduced insulin independence rates (p<0.0001).

Chronic pancreatitis as indication for auto-ITx reduced insulin independence rates (p=0.0008), while tumors as indication increased insulin independence rates (p<0.0001).

Absence of a prior ERCP improved insulin independence rates (p=0.0007), as did absence of prior intervention (p=0.0002).

Recipients 18-35 years old (Exhibit 5-1C)

Islet particle count ≥500,000 (p=0.0013), IEQs infused ≥275,000 (p=0.0023), and IEQs/kg ≥3,000 (p=0.0004) were all associated with higher rates of insulin independence in this age group. Islets IEQs/kg recipient <5.15k reduced insulin independence rates (p=0.0053), as did the absence of islet purification (p=0.0008).

Chronic pancreatitis as indication for auto-ITx reduced insulin independence rates (p=0.0093).

Recipients <18 years old

These groups had too small sample size to uncover any factors associated with improved levels of insulin independence following transplantation.

Younger age was a significant predictor of higher **C-peptide≥0.3 ng/mL** prevalence over five years post auto-ITx with (Exhibit 5-2A). For the ≥35-year-old patients, many of the same variables that influenced insulin independence rates also influenced rates of C-peptide≥0.3 mg/dL (Exhibit 5-2B). Lower Fasting Blood Glucose and HbA1c and higher fasting C-peptide at baseline, being female, ≥500K IEQs infused, and IEQs/kg ≥3,000 were all associated with improved retention of C-peptide≥0.3ng/mL over 5 years. In the 18-35 year-olds, higher number of islet particles at count, IEQs infused, and IEQs/kg improved rates of C-peptide≥0.3ng/mL (Exhibit 5-2C). Again due to sample size, there were no detectable factors presented 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. Prevalence rates declined over five years post-transplant, but less so in younger age groups, with those 12-<18 years old maintaining ~80% compared to lower percentages in older groups (Exhibit 5-3A). In the ≥35 age group, female recipients ($p<0.0001$) and donors ($p<0.0001$) and those with absence of pancreatitis as indication ($p=0.0008$) showed higher rates of FBG 60-140 (Exhibit 5-3B).

Most auto-ITx patients had **HbA1c<7.0%** at baseline. These rates declined to between 50% and 70% in children <12-year-olds and adults ≥35 experienced the greatest decline (Exhibit 5-4A). In the ≥35 age group, female donors, female recipients, and those with lower Fasting Blood Glucose and HbA1c at baseline were more likely to have HbA1c<7.0% (Exhibit 5-4B). Among the 18-35 age group, female donors, female recipients, and those who received ≥3,000 IEQs/kg showed higher rates of HbA1c <7.0%(Exhibit 5-4C).

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 5-5A).

Insulin dose (Exhibit 5-6) 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 5-7) varied substantially by total IEQs for all infusions with more IEQs associated with higher levels of fasting C-peptide ($p<0.0001$), and pancreatitis etiology.

HbA1c boxplots (Exhibit 5-8) varied by era, age group and pancreatitis etiology.

Fasting blood glucose as a continuous variable (Exhibit 5-9) varied by era, pancreatitis etiology and by age with worse outcomes in those aged ≥35.

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.

Exhibit 5-1A
Prevalence of Insulin Independence Post Last Infusion by Age Group (p=<.0001)

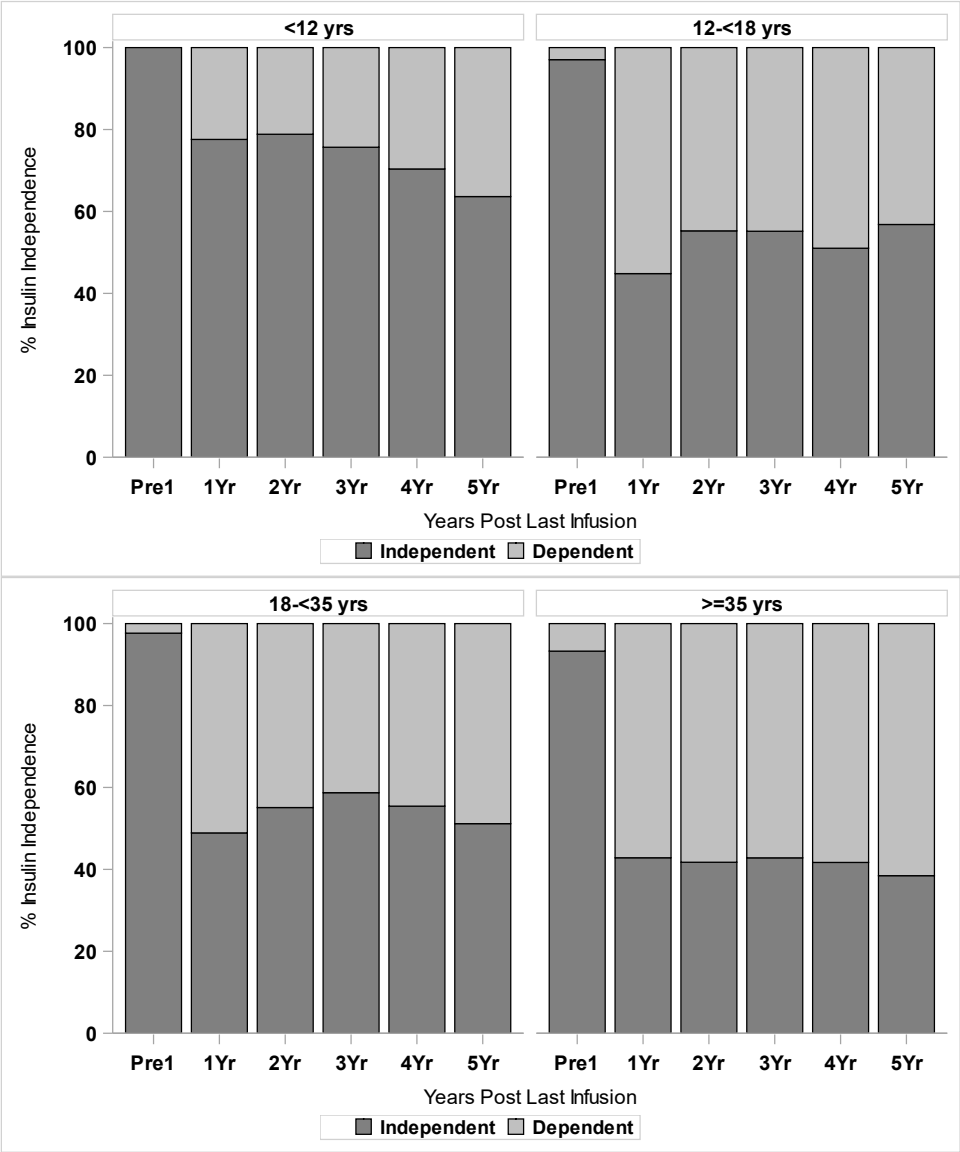
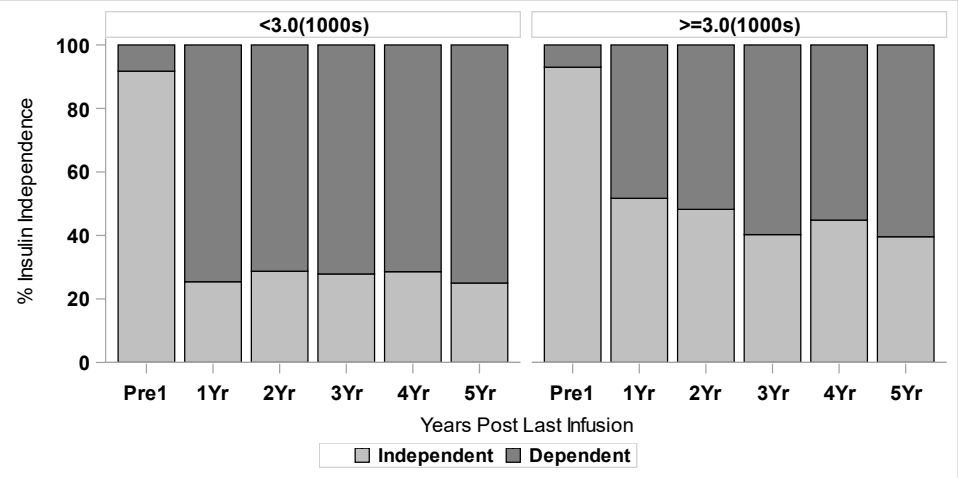


Exhibit 5-1B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Insulin Independence Post Last Infusion among Recipients Aged 35 Years and Older

IEQs/kg (p=0.0007)



Baseline FBG (p=<.0001)

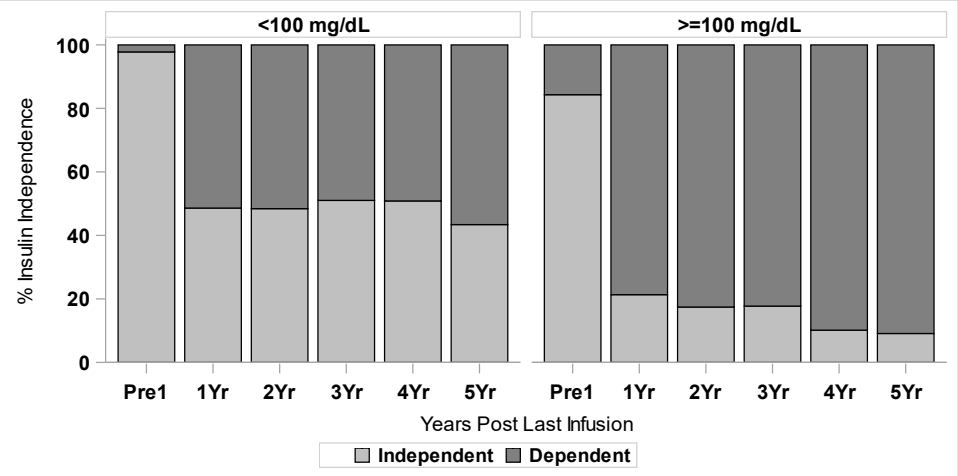
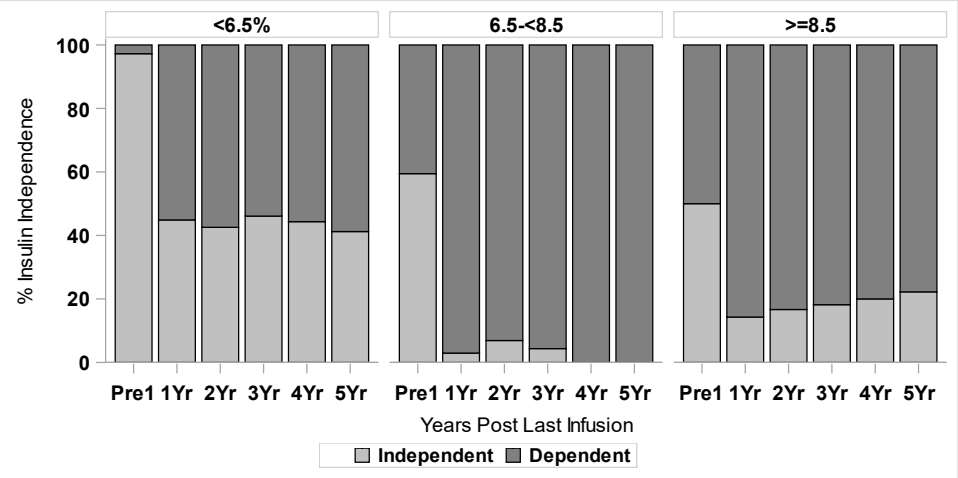


Exhibit 5-1B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Insulin Independence Post Last Infusion among Recipients Aged 35 Years and Older

Baseline HbA1c (p=0.0014)



Baseline retinopathy (p=<.0001)

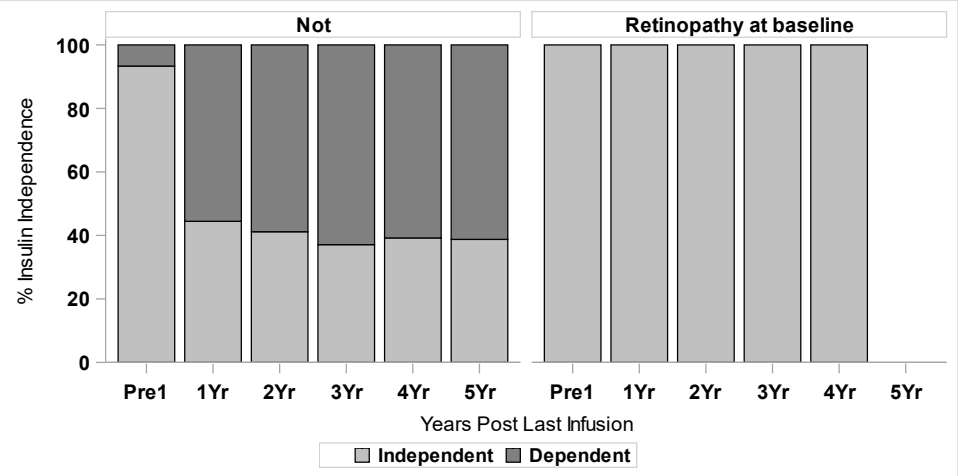
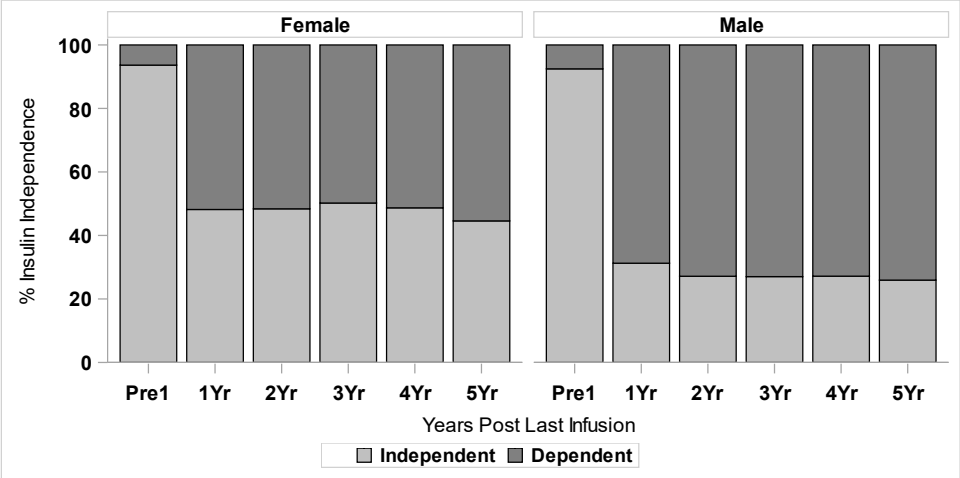


Exhibit 5-1B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Insulin Independence Post Last Infusion among Recipients Aged 35 Years and Older

Donor gender (p=<.0001)



Any ERCP (p=0.0016)

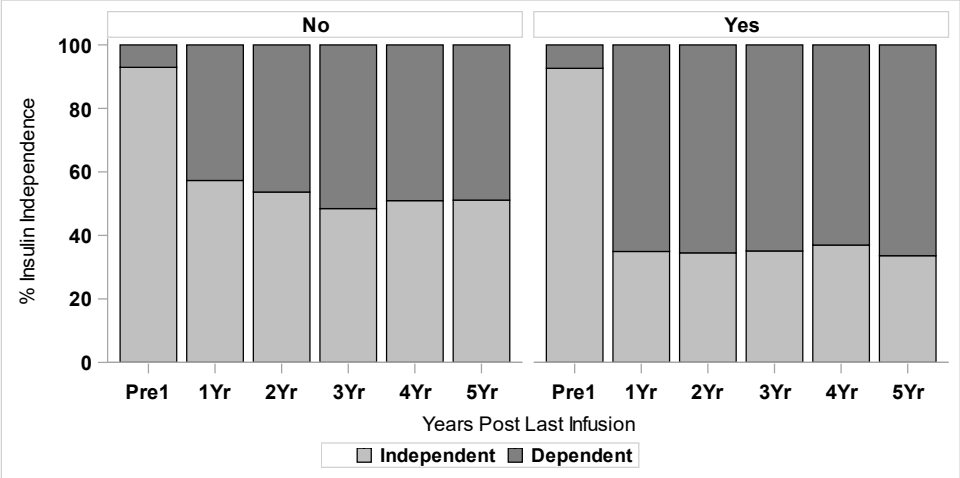
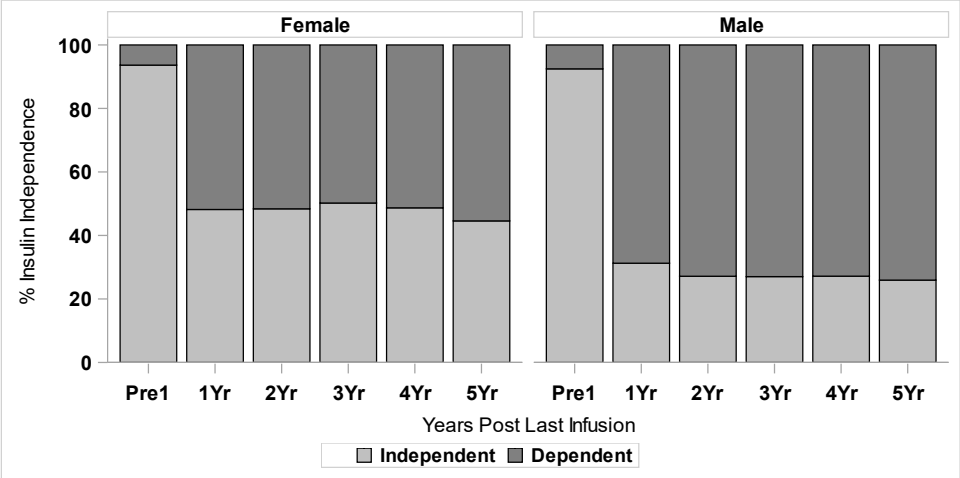


Exhibit 5-1B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Insulin Independence Post Last Infusion among Recipients Aged 35 Years and Older

Gender (p=<.0001)



ERCP (p=0.0007)

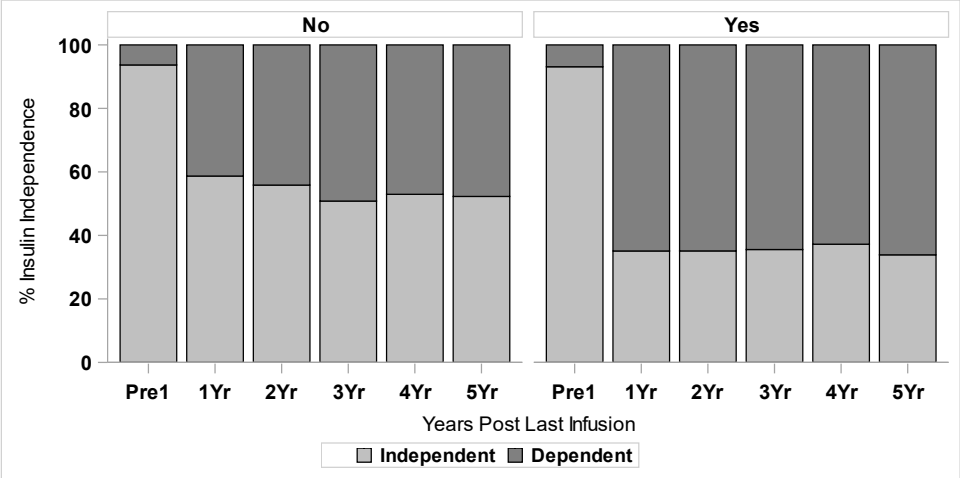
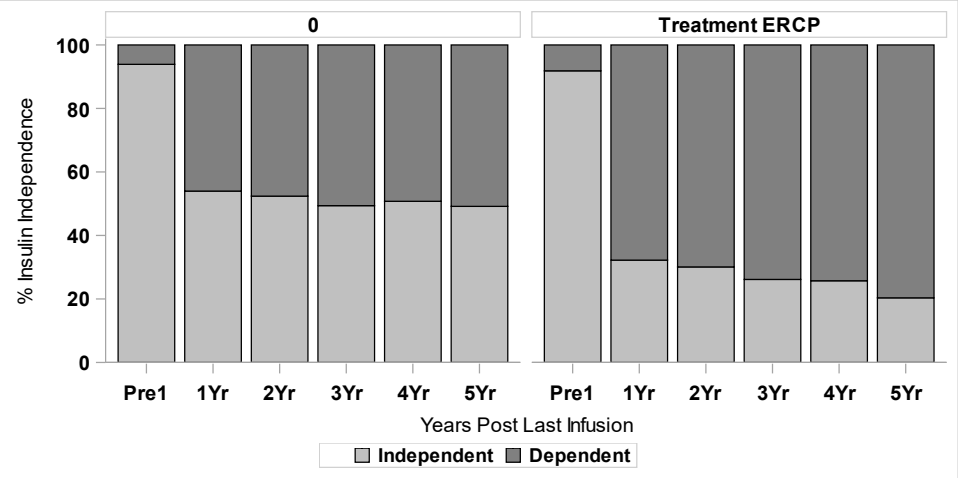


Exhibit 5-1B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Insulin Independence Post Last Infusion among Recipients Aged 35 Years and Older

Treatment ERCP (0-No 1-Yes) (p=0.0001)



Islets IEQs all infusions (p=0.0010)

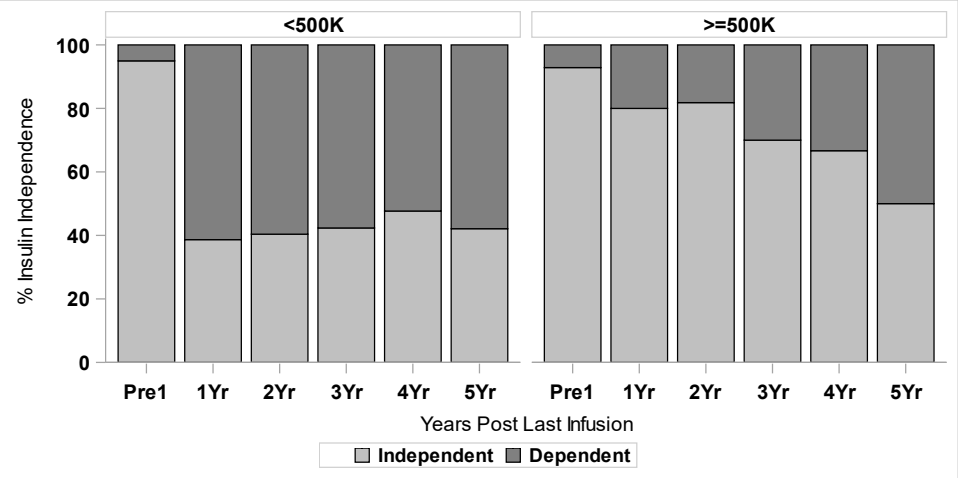
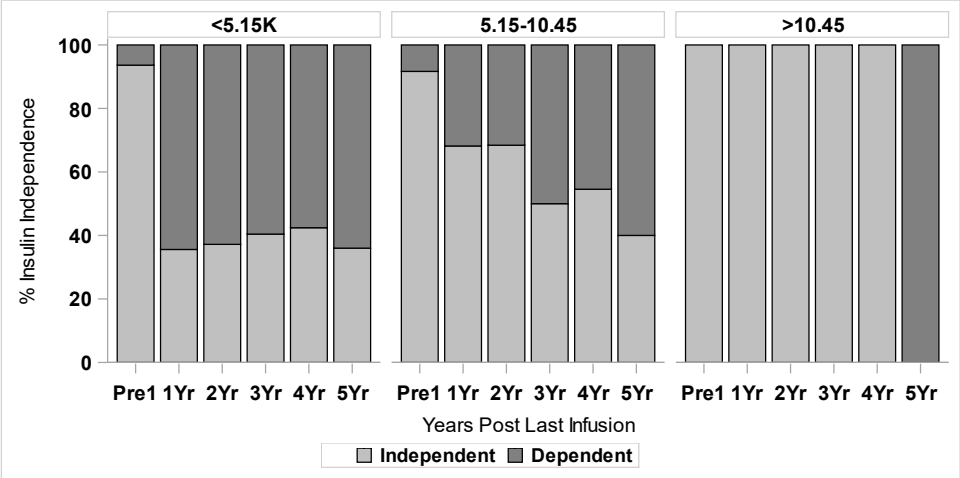


Exhibit 5-1B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Insulin Independence Post Last Infusion among Recipients Aged 35 Years and Older

Islets IEQs/kg recipient (p=<.0001)



Islets IEQs infused (p=0.0032)

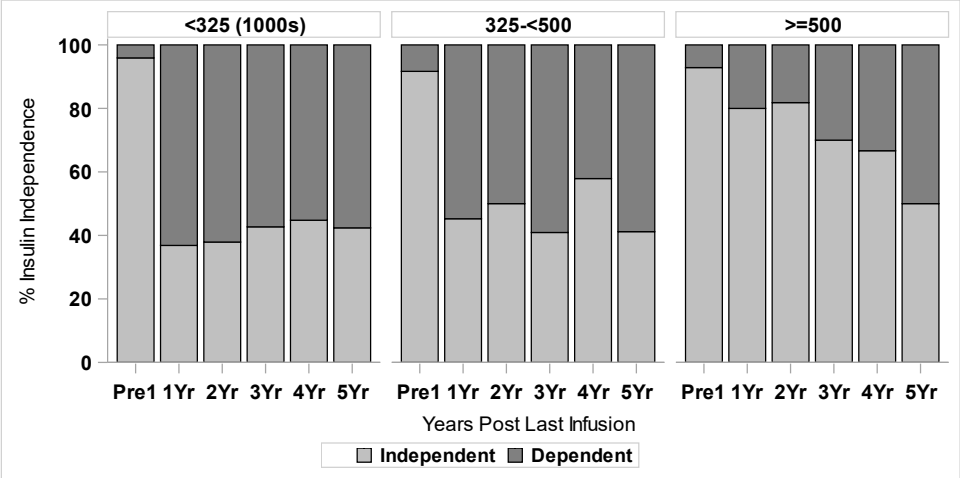
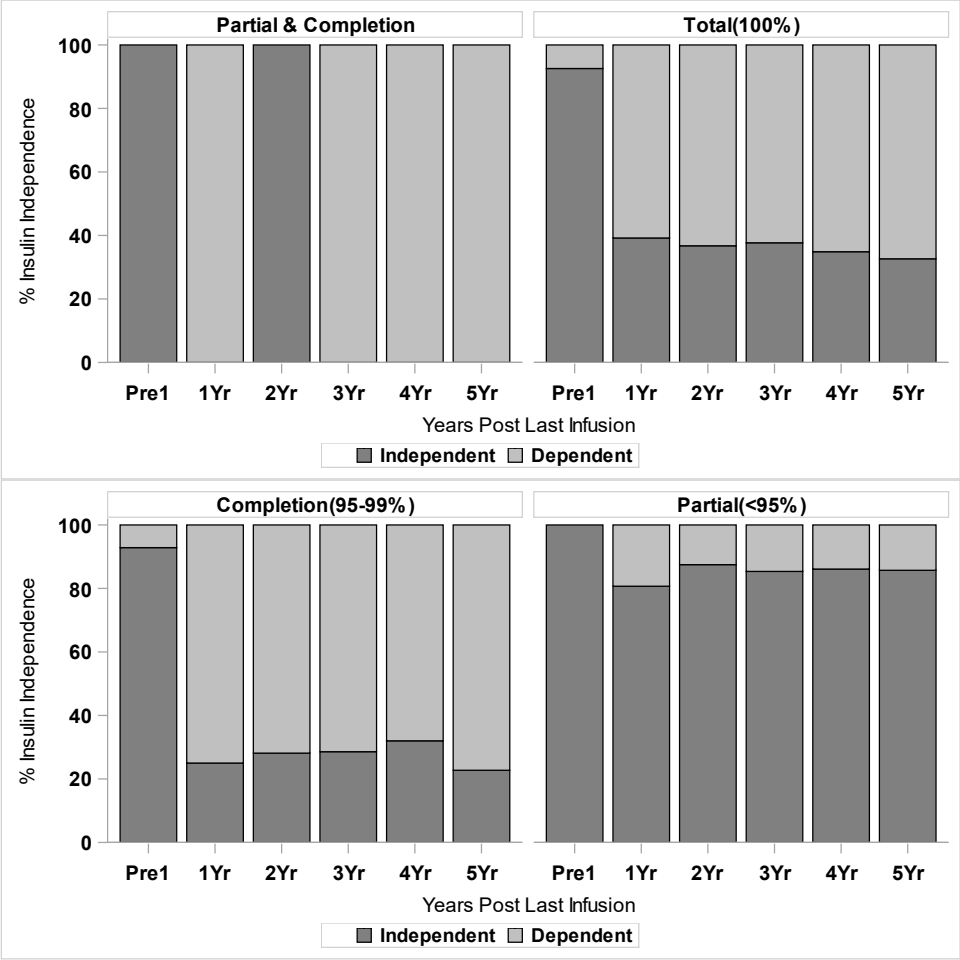


Exhibit 5-1B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Insulin Independence Post Last Infusion among Recipients Aged 35 Years and Older

Pancreatectomy type (p=<.0001)



Prior Intervention (p=0.0002)

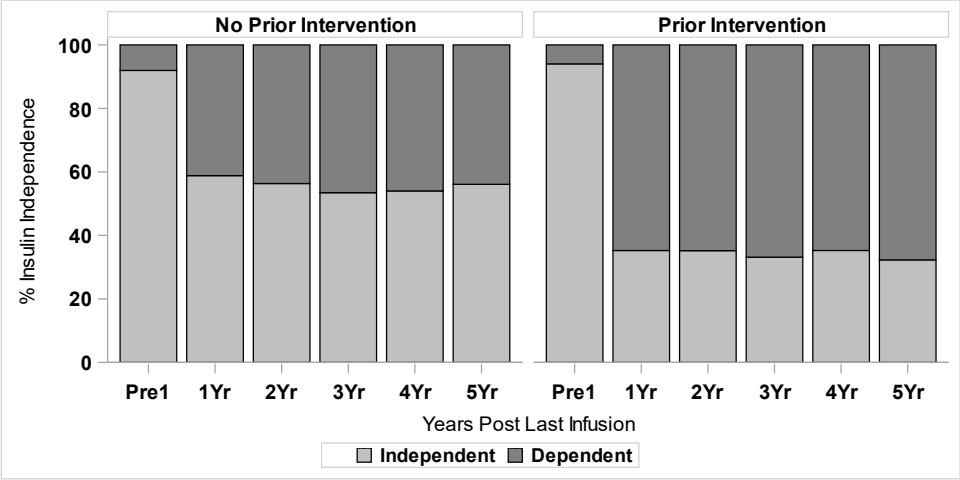
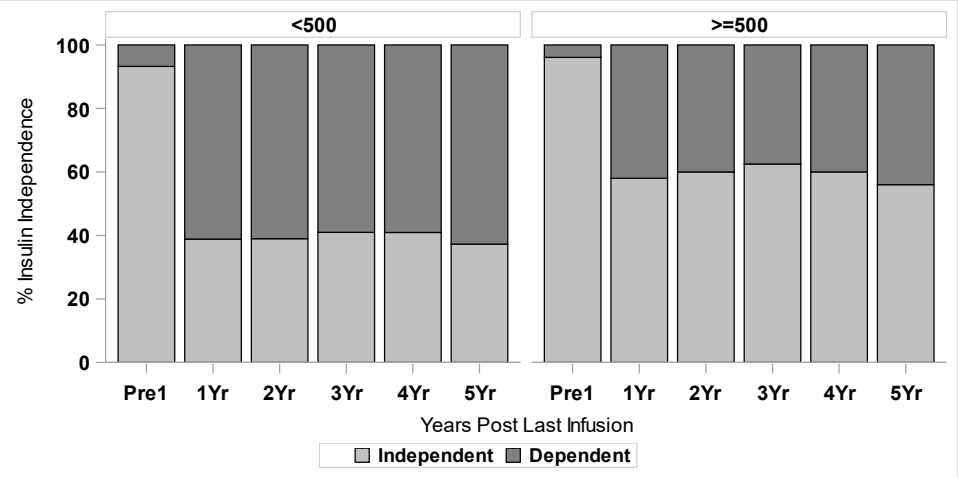


Exhibit 5-1B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Insulin Independence Post Last Infusion among Recipients Aged 35 Years and Older

Islets particle count (p=0.0011)



Total infusions (p=0.0072)

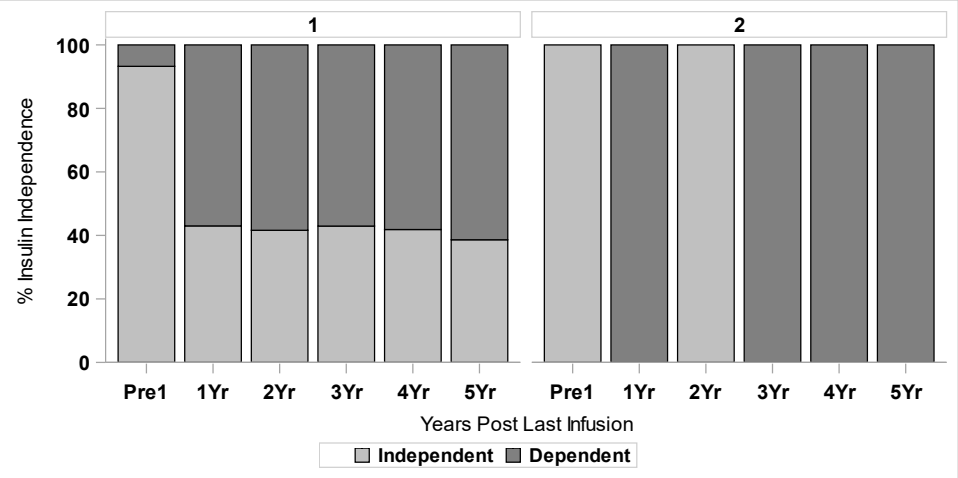
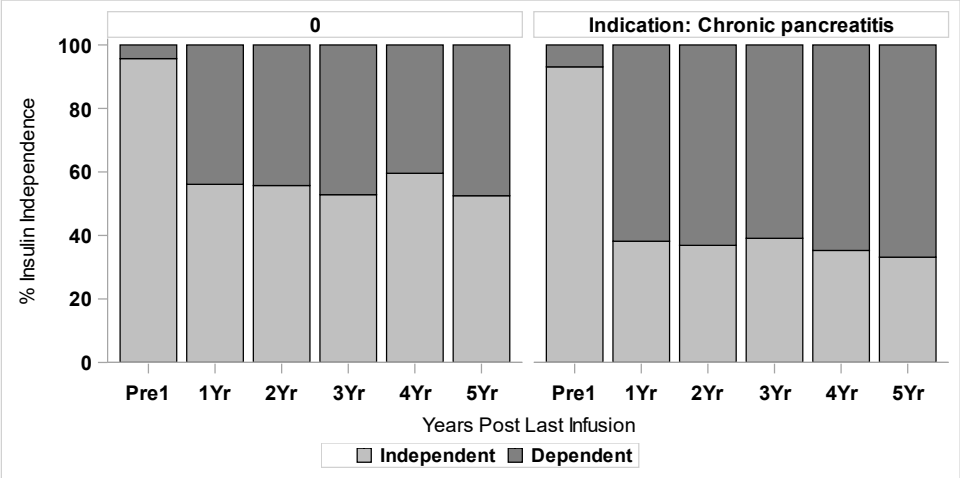


Exhibit 5-1B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Insulin Independence Post Last Infusion among Recipients Aged 35 Years and Older

Indication: Chronic pancreatitis (0-No 1-Yes) (p=0.0008)



Indication: Tumors (0-No 1-Yes) (p=<.0001)

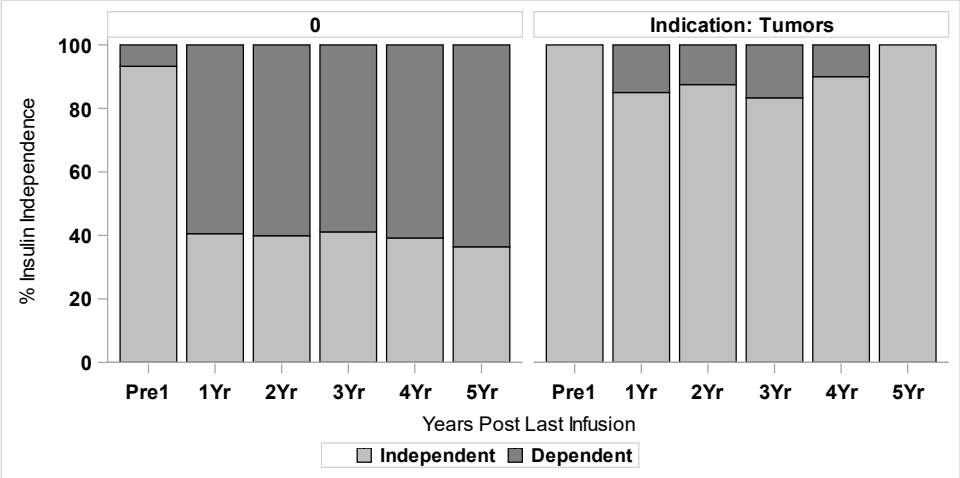
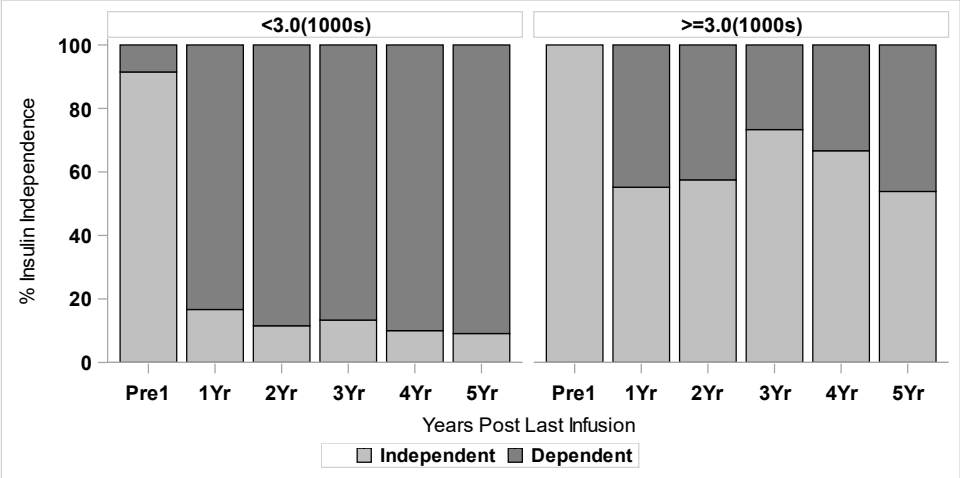


Exhibit 5-1C
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Insulin Independence Post Last Infusion among Recipients Aged 18 to 35 Years

IEQs/kg (p=0.0004)



IEQs (p=0.0023)

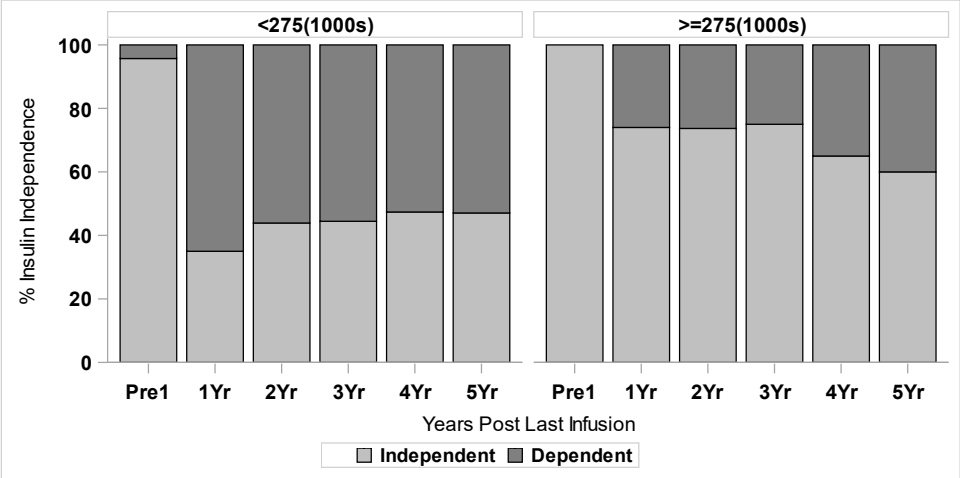
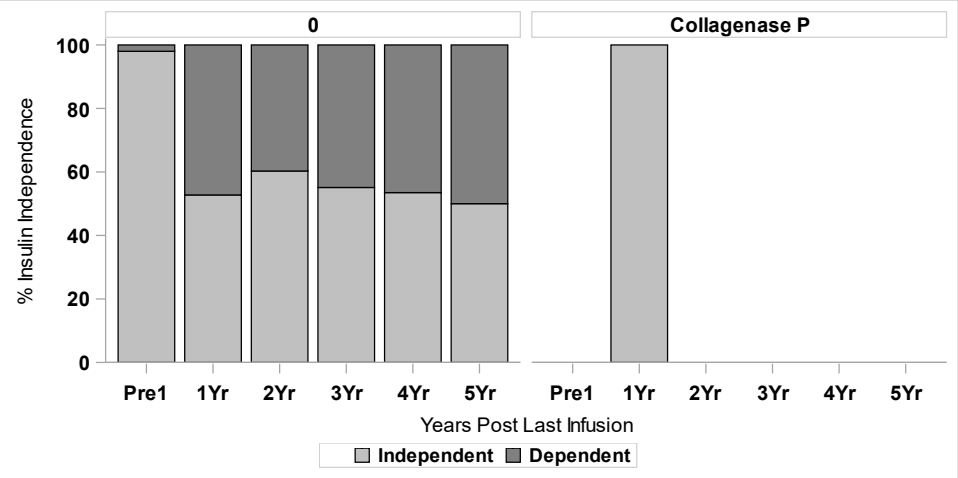


Exhibit 5-1C
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Insulin Independence Post Last Infusion among Recipients Aged 18 to 35 Years

Collagenase P (p=<.0001)



Era (p=0.0014)

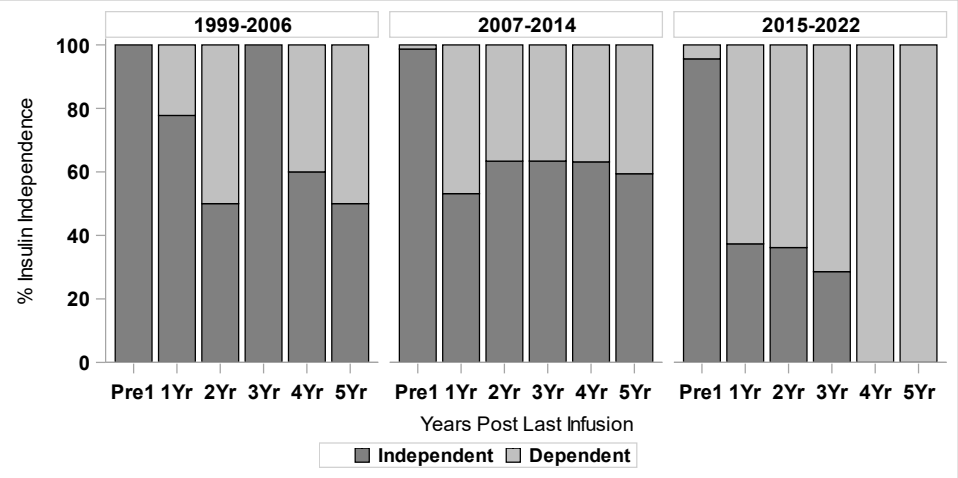
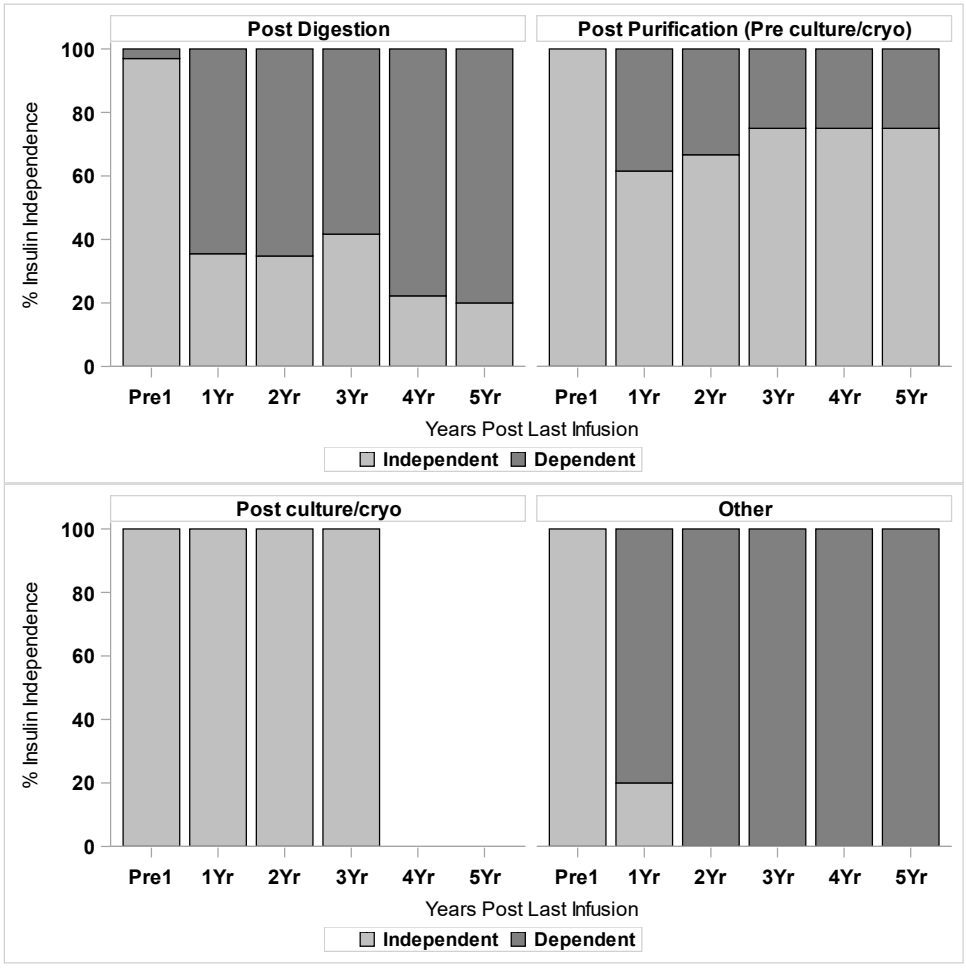


Exhibit 5-1C
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Insulin Independence Post Last Infusion among Recipients Aged 18 to 35 Years

Time of IEQ count (p=<.0001)



Islets IEQs/kg recipient (p=0.0053)

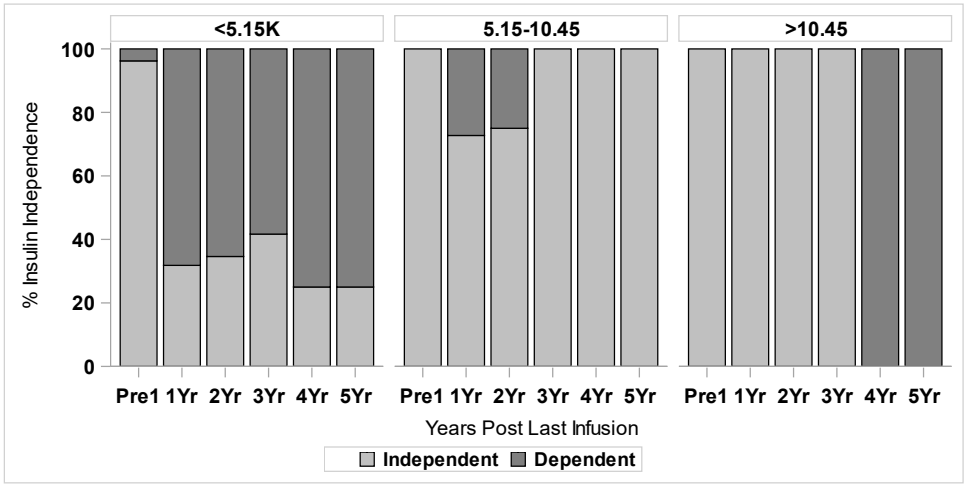
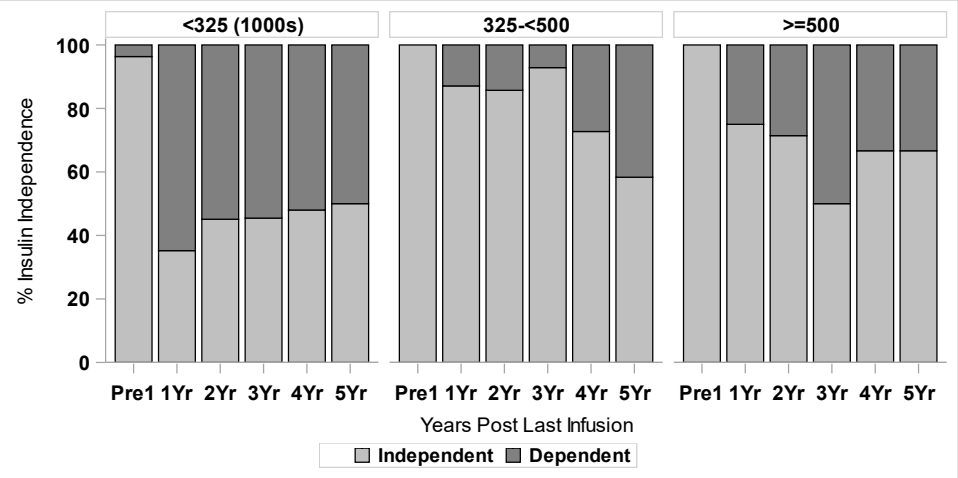


Exhibit 5-1C
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Insulin Independence Post Last Infusion among Recipients Aged 18 to 35 Years

Islets IEQs infused (p=0.0001)



Islet purification (p=0.0008)

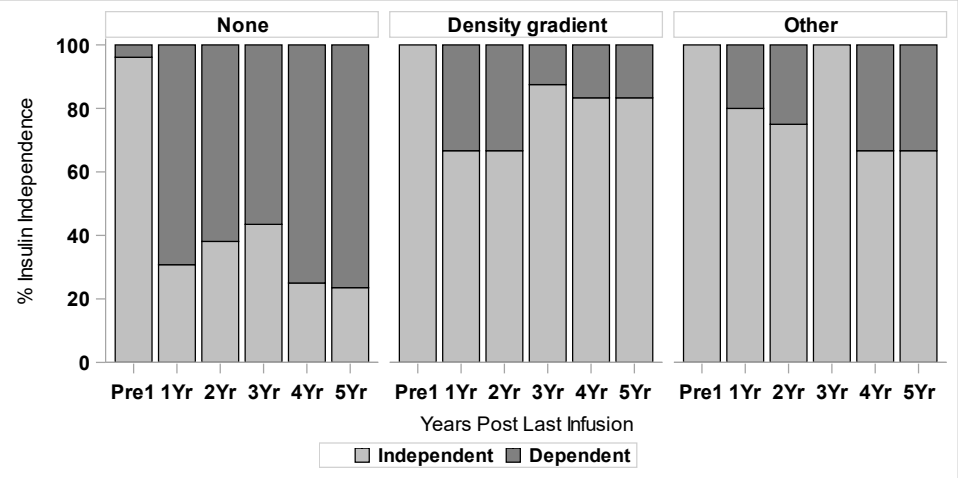
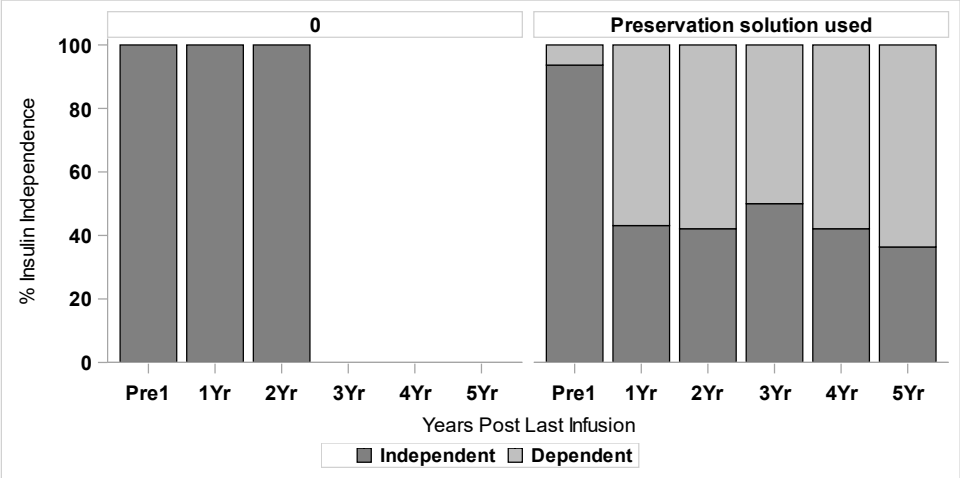


Exhibit 5-1C
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Insulin Independence Post Last Infusion among Recipients Aged 18 to 35 Years

Preservation solution used (0-No 1-Yes) (p=<.0001)



Pancreatectomy type (p=<.0001)

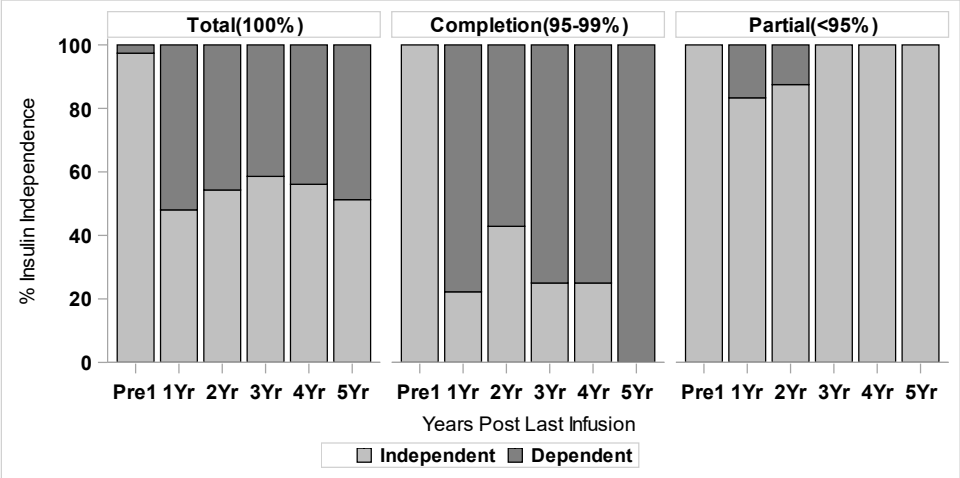
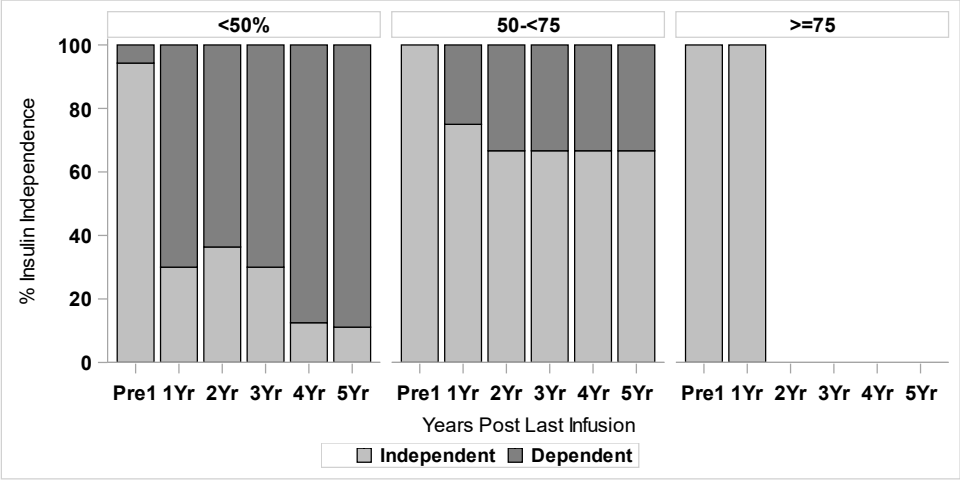


Exhibit 5-1C
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Insulin Independence Post Last Infusion among Recipients Aged 18 to 35 Years

Islets purity (p=0.0001)



Prior Whipple (0-No 1-Yes) (p=0.0001)

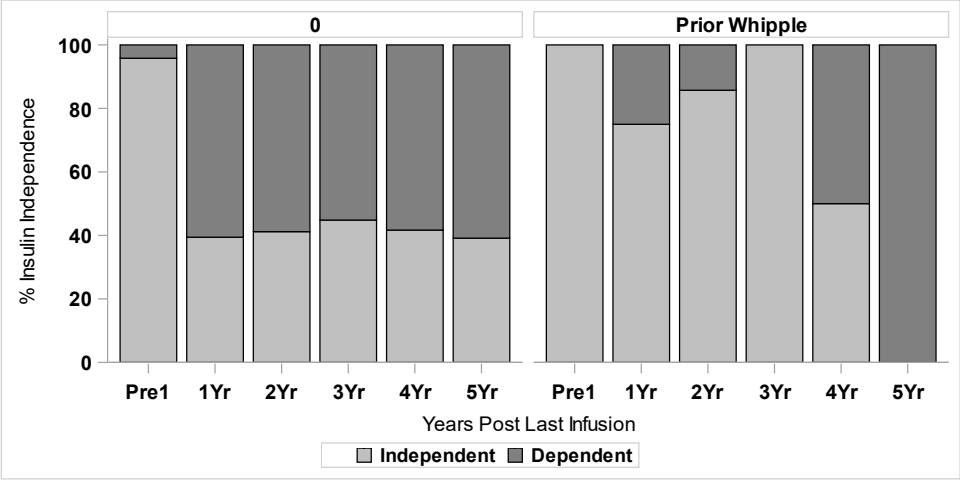
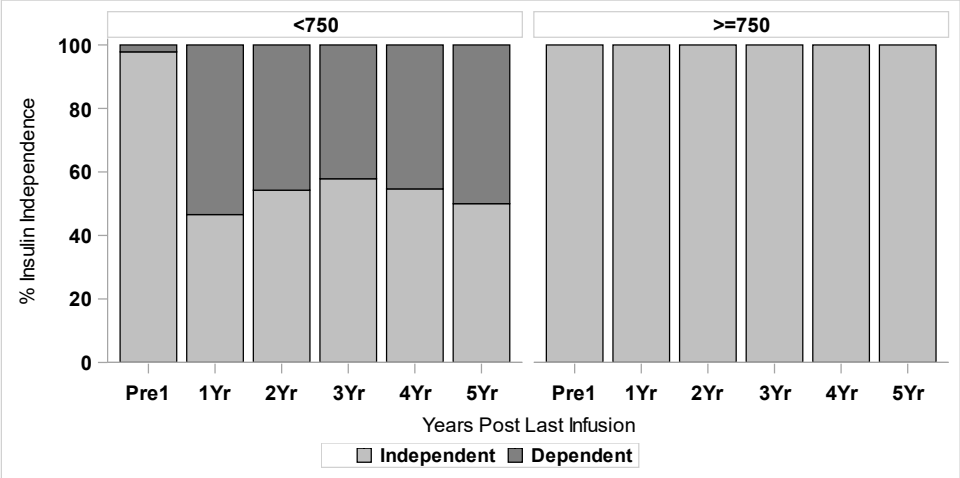


Exhibit 5-1C
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Insulin Independence Post Last Infusion among Recipients Aged 18 to 35 Years

Islets IEQ count (p=<.0001)



Islets particle count (p=0.0013)

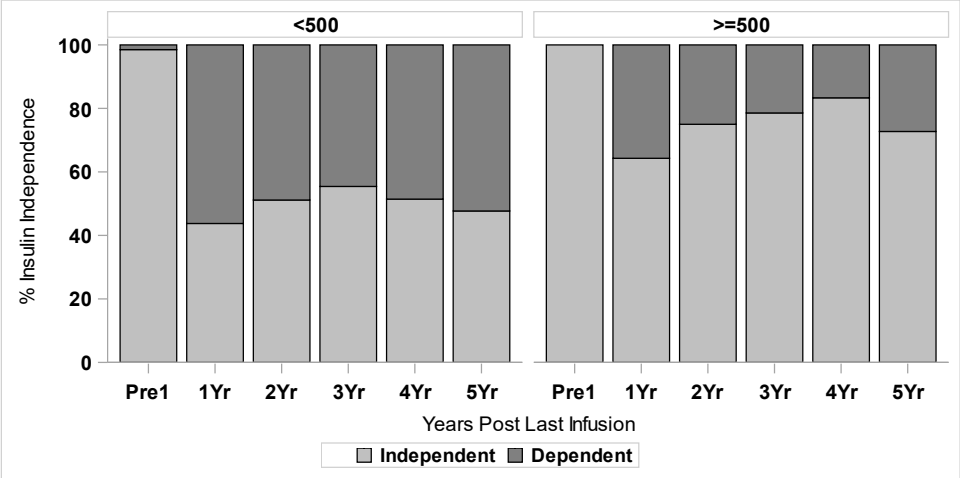
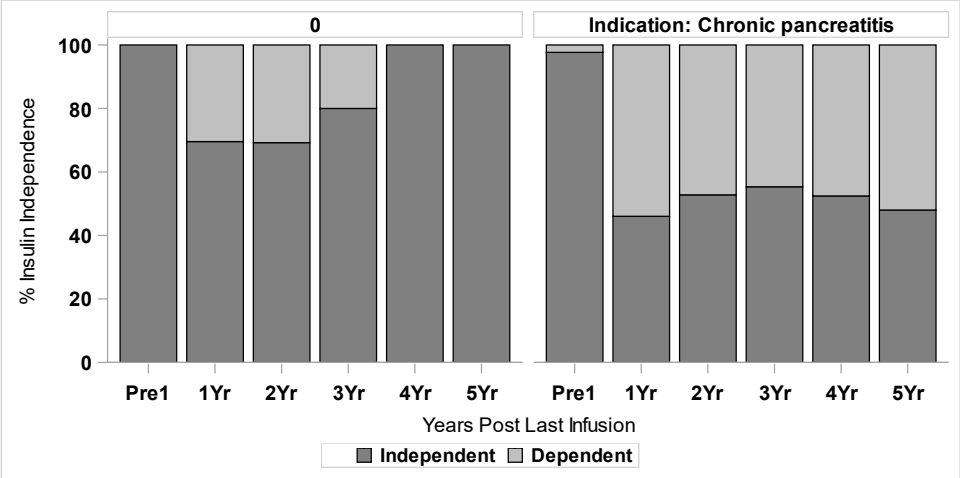


Exhibit 5-1C
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Insulin Independence Post Last Infusion among Recipients Aged 18 to 35 Years

Indication: Chronic pancreatitis (0-No 1-Yes) (p=0.0093)



Indication: Cancer (0-No 1-Yes) (p=<.0001)

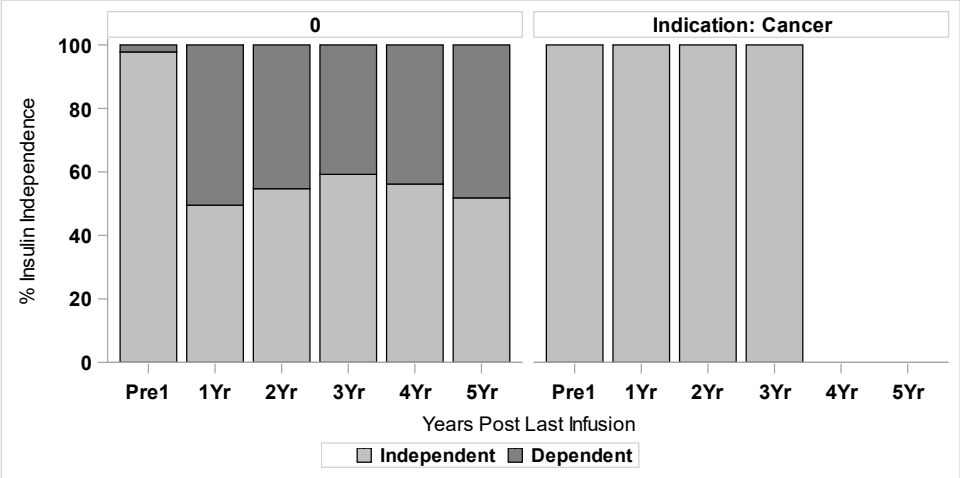


Exhibit 5-1C
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Insulin Independence Post Last Infusion among Recipients Aged 18 to 35 Years

Indication: Tumors (0-No 1-Yes) (p=<.0001)

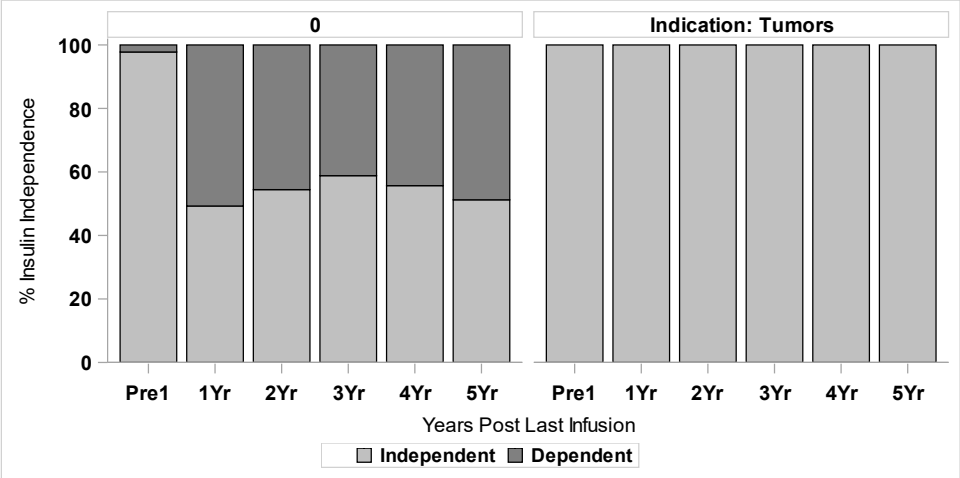


Exhibit 5-2A
Prevalence of Fasting C-peptide>=0.3 ng/mL Post Last Infusion by Age Group (p=<.0001)

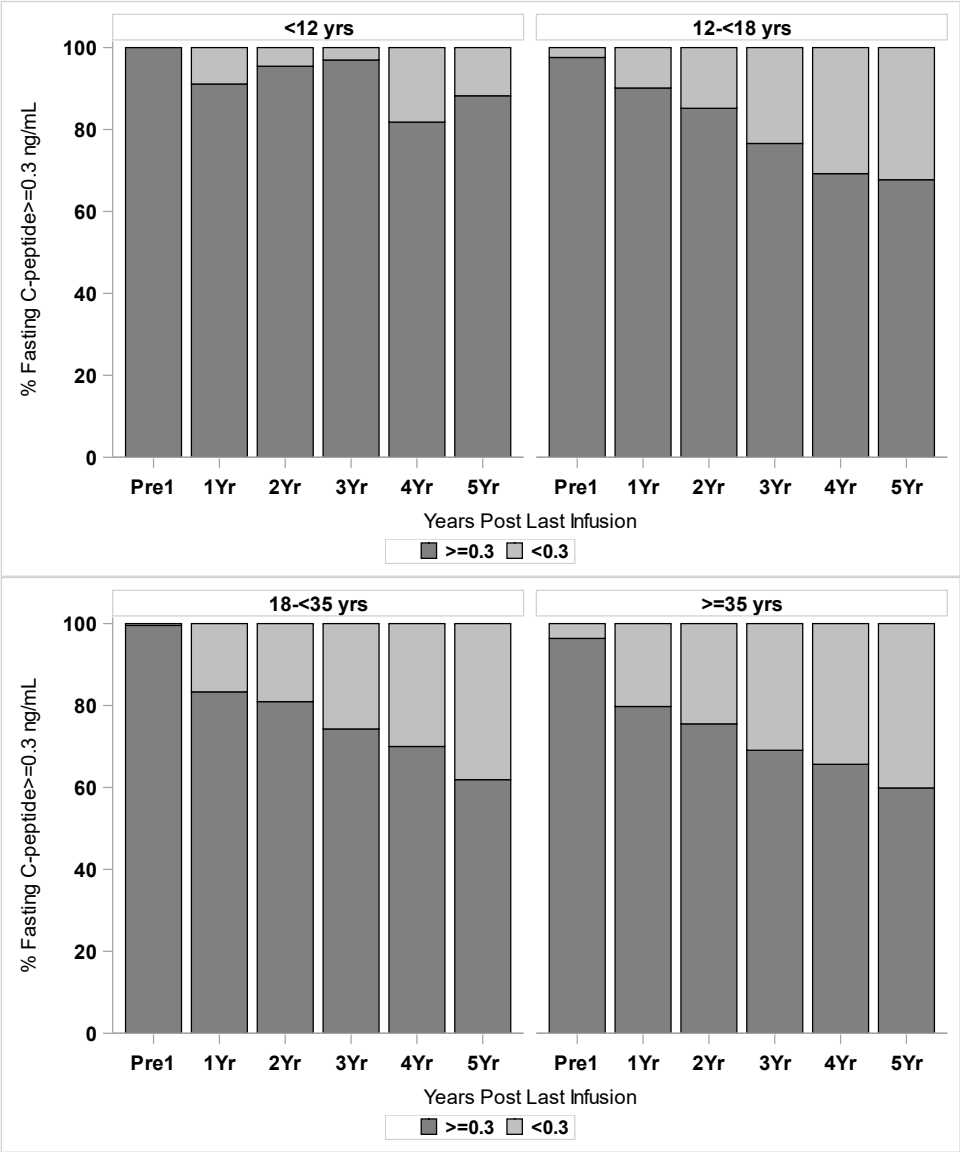
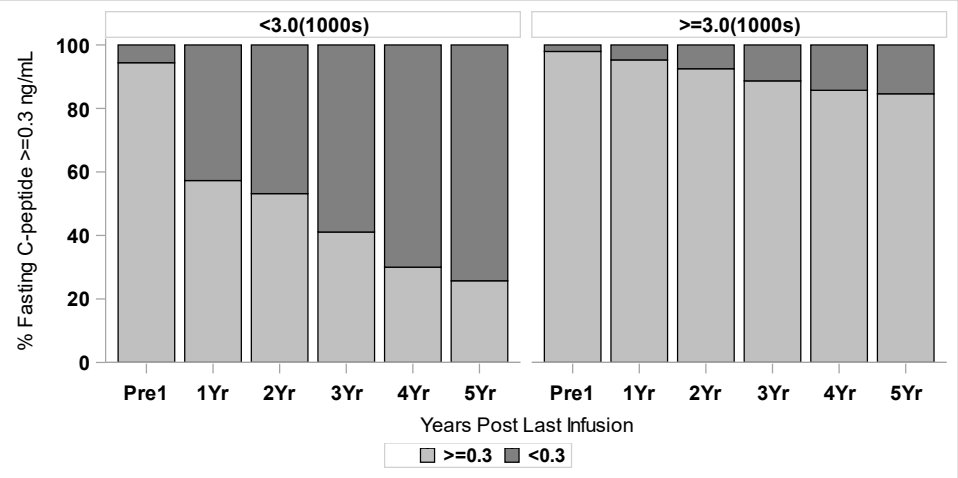


Exhibit 5-2B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Fasting C-peptide>=0.3 ng/mL Post Last Infusion among Recipients Aged 35 Years and Older

IEQs/kg (p=<.0001)



IEQs (p=<.0001)

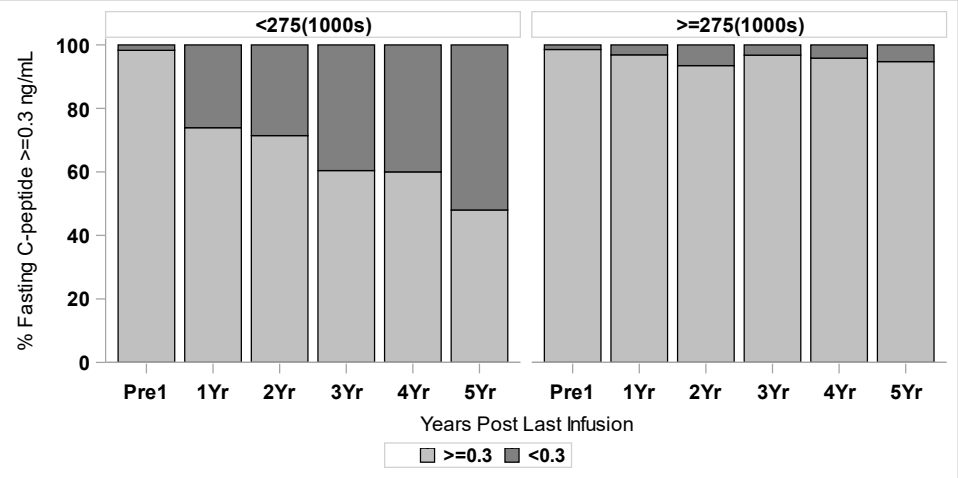
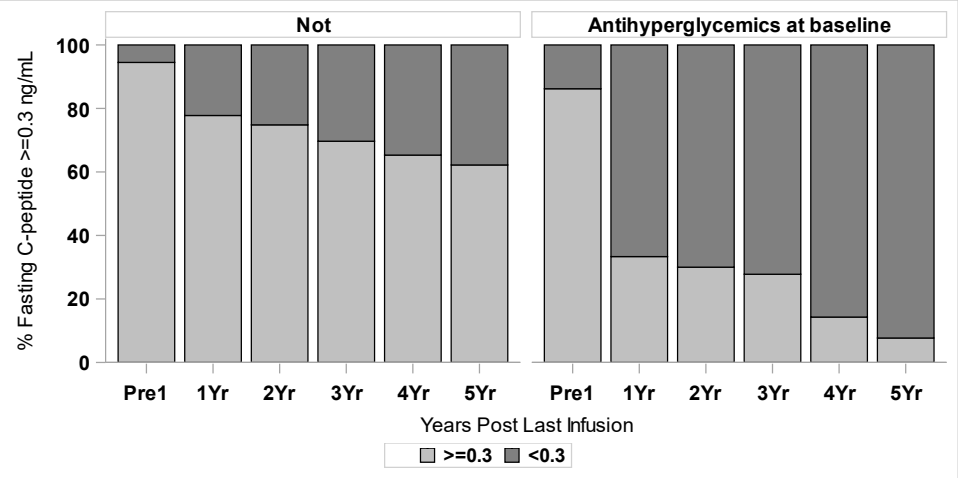


Exhibit 5-2B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Fasting C-peptide>=0.3 ng/mL Post Last Infusion among Recipients Aged 35 Years and Older

Baseline antihyperglycemics (p=0.0029)



Baseline fasting C-peptide (p=0.0090)

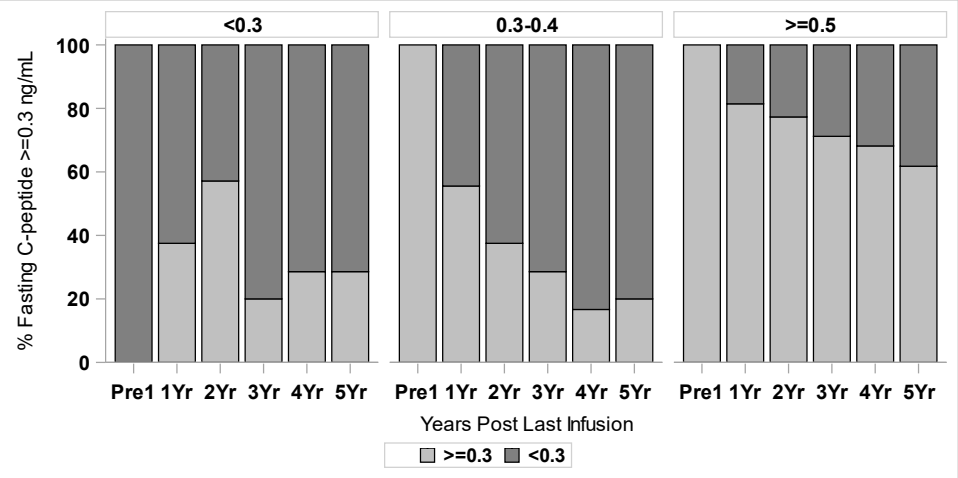
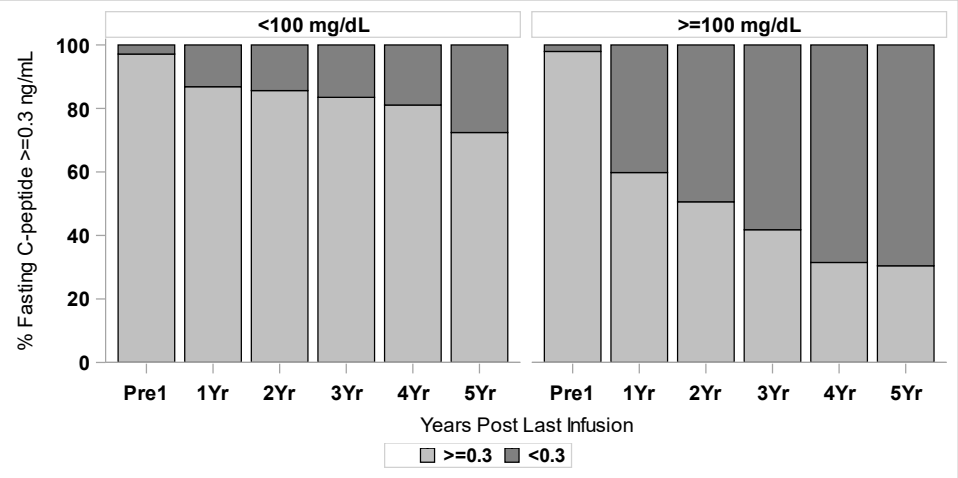


Exhibit 5-2B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Fasting C-peptide>=0.3 ng/mL Post Last Infusion among Recipients Aged 35 Years and Older

Baseline FBG (p=<.0001)



Baseline HbA1c (p=<.0001)

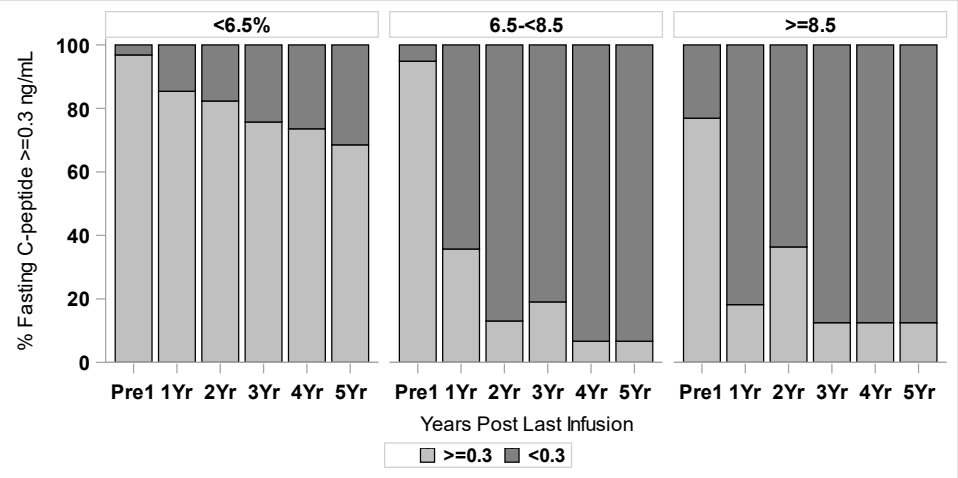
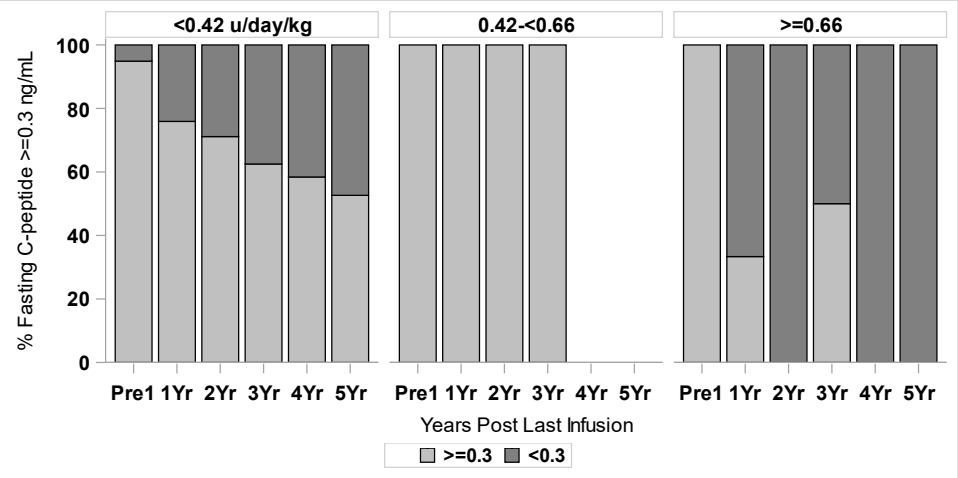


Exhibit 5-2B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Fasting C-peptide>=0.3 ng/mL Post Last Infusion among Recipients Aged 35 Years and Older

Baseline insulin (U/kg/day) (p=<.0001)



Baseline peripheral neuropathy (p=<.0001)

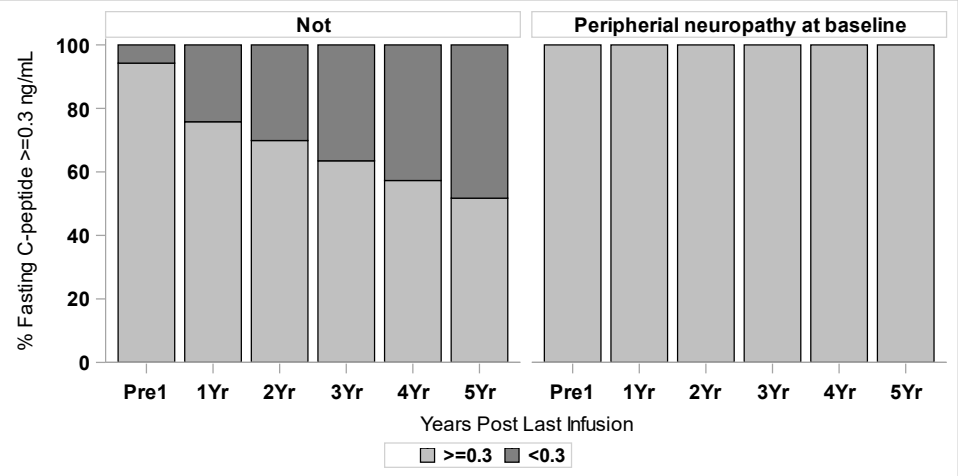
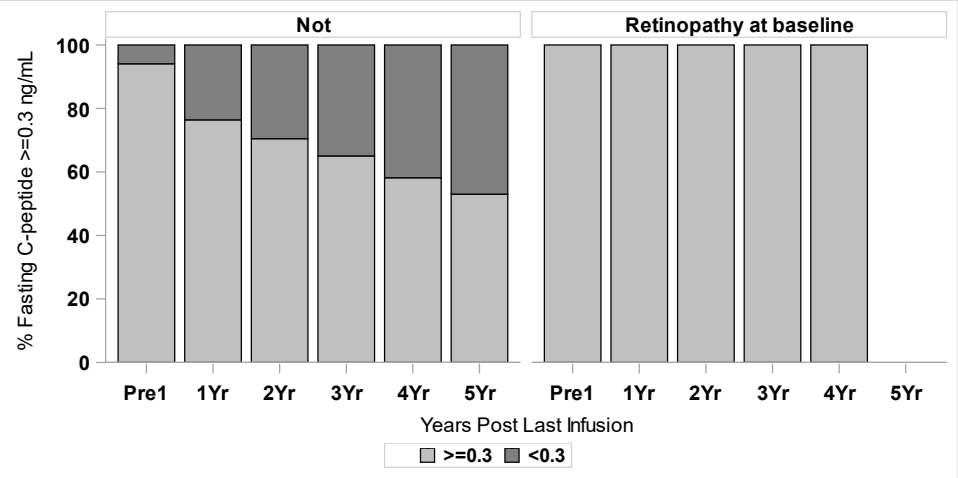


Exhibit 5-2B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Fasting C-peptide>=0.3 ng/mL Post Last Infusion among Recipients Aged 35 Years and Older

Baseline retinopathy (p=<.0001)



Baseline CKD GFR (p=<.0001)

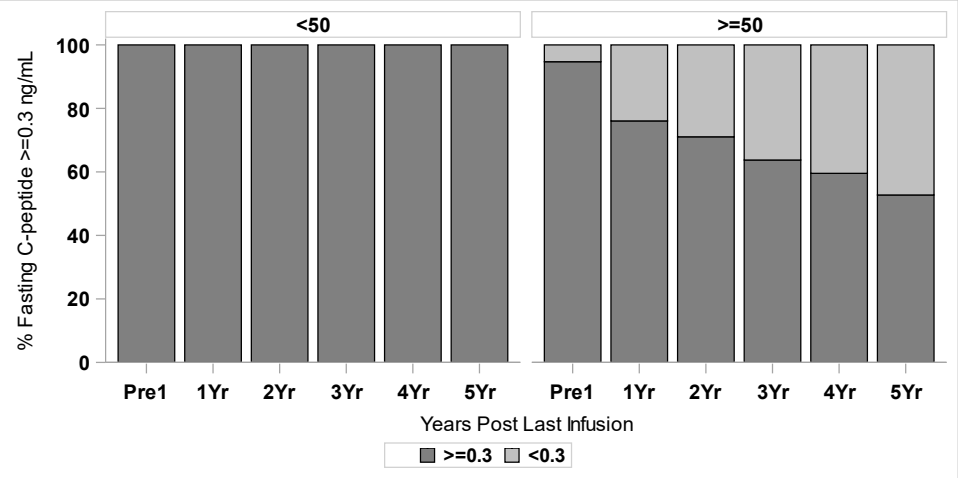
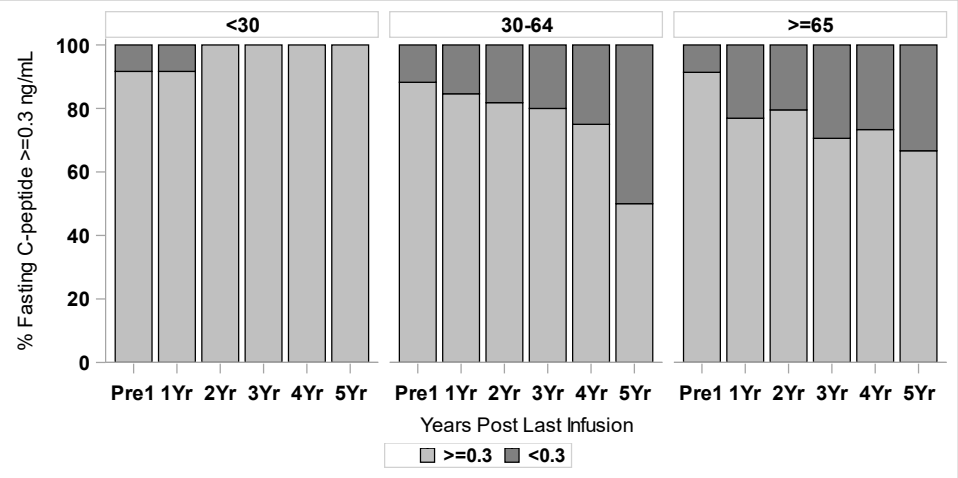


Exhibit 5-2B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Fasting C-peptide>=0.3 ng/mL Post Last Infusion among Recipients Aged 35 Years and Older

Baseline Triglycerides (p=0.0081)



Donor gender (p=0.0005)

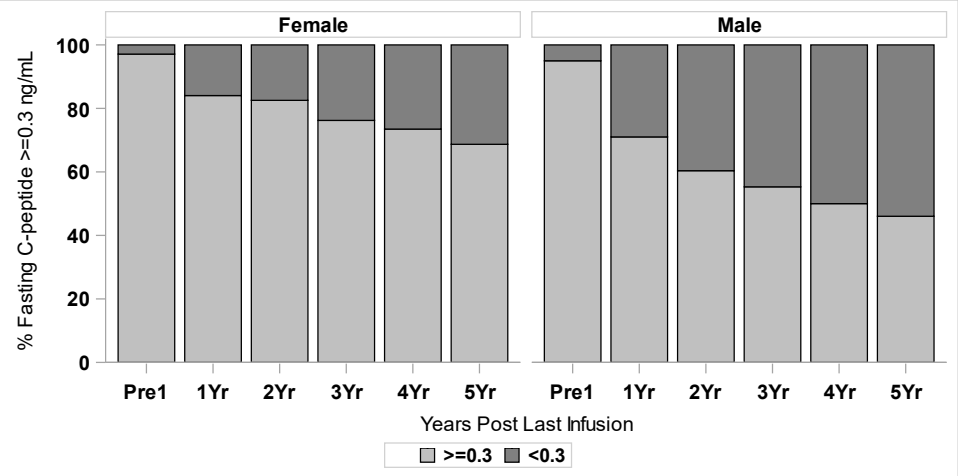
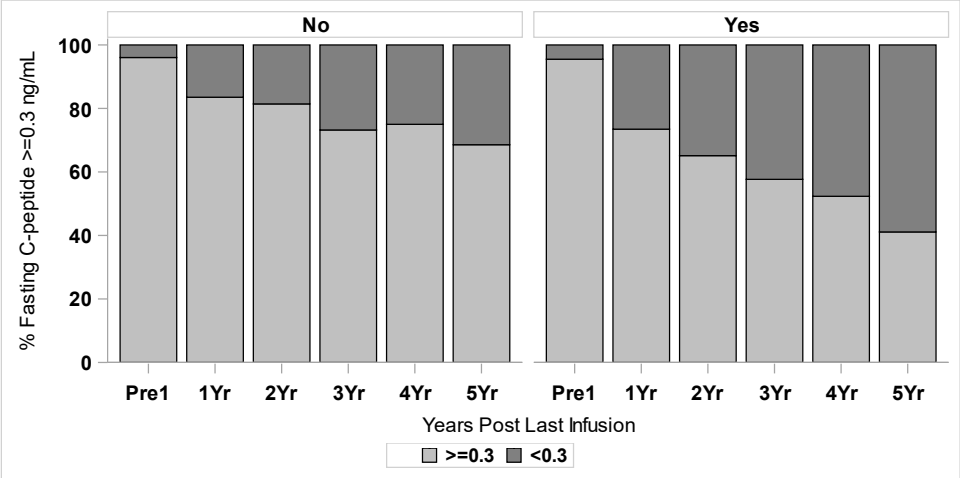


Exhibit 5-2B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Fasting C-peptide>=0.3 ng/mL Post Last Infusion among Recipients Aged 35 Years and Older

Any ERCP (p=0.0064)



Gender (p=0.0005)

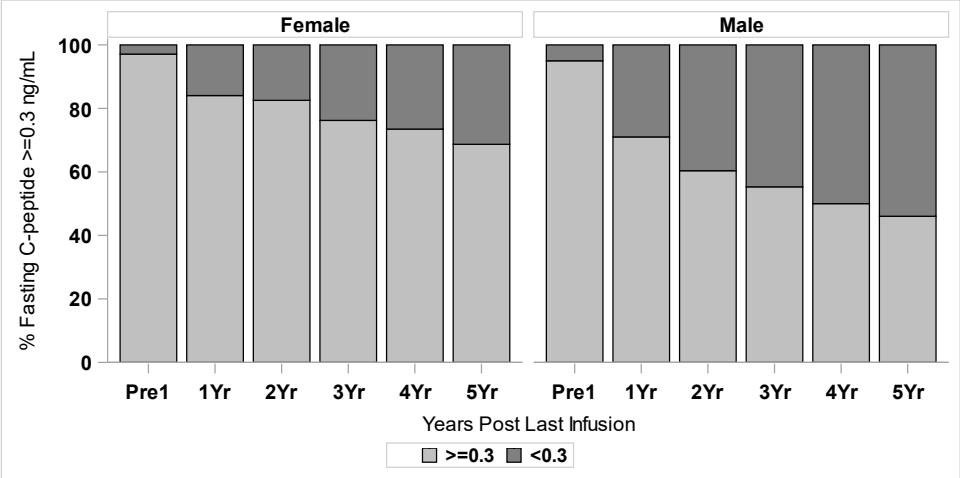
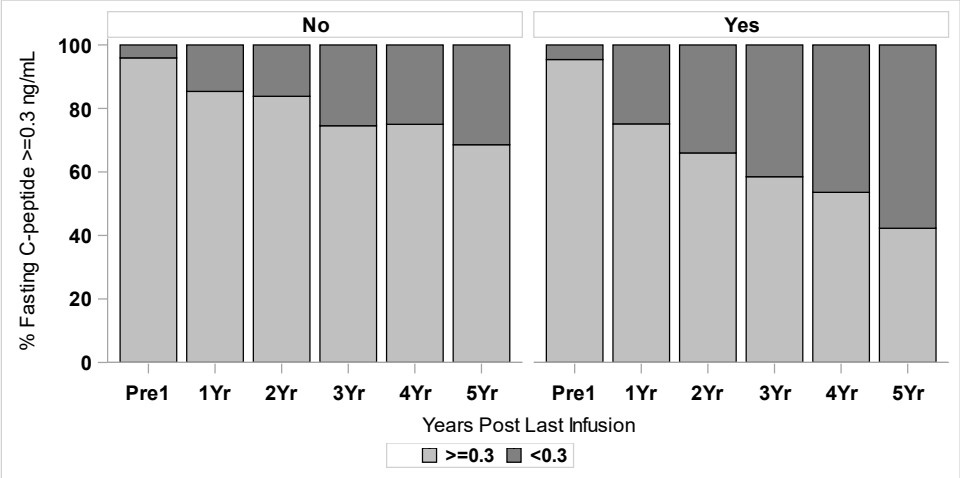


Exhibit 5-2B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Fasting C-peptide>=0.3 ng/mL Post Last Infusion among Recipients Aged 35 Years and Older

ERCP (p=0.0055)



Treatment ERCP (0-No 1-Yes) (p=0.0005)

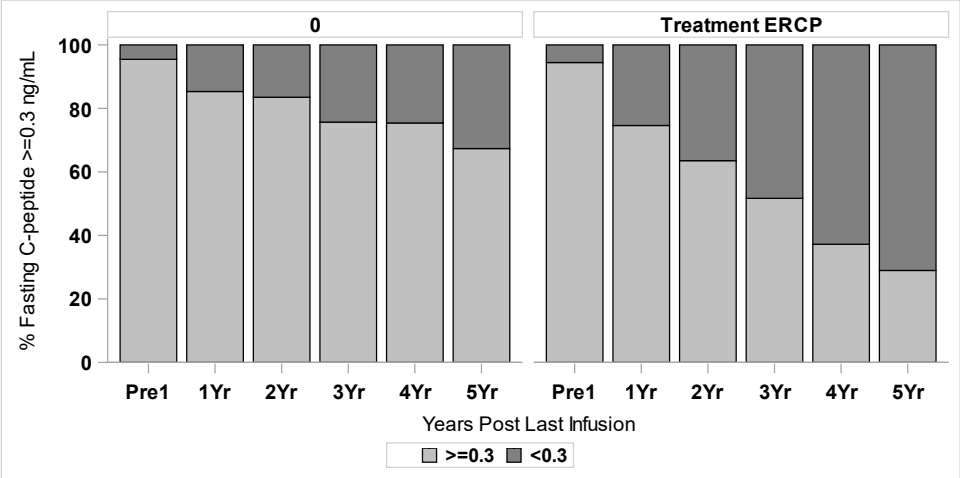
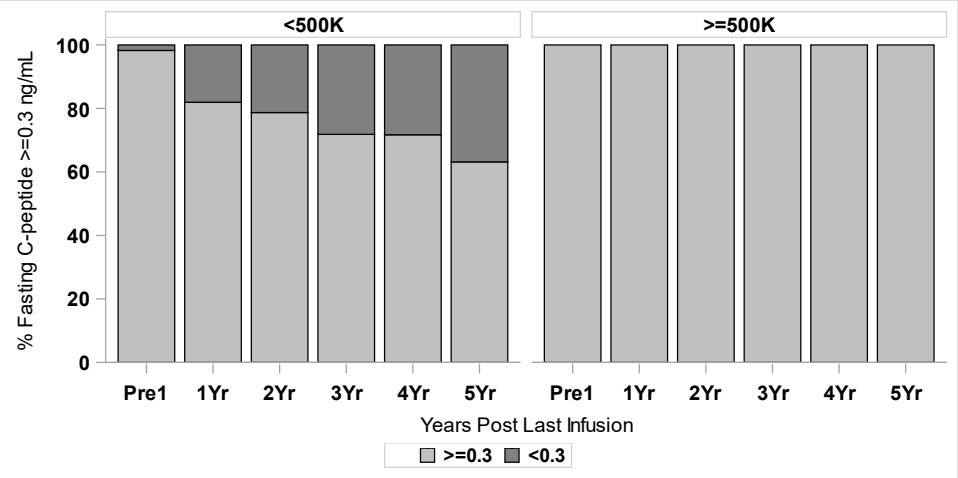


Exhibit 5-2B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Fasting C-peptide>=0.3 ng/mL Post Last Infusion among Recipients Aged 35 Years and Older

Islets IEQs all infusions (p=<.0001)



Islets IEQs/kg recipient (p=0.0002)

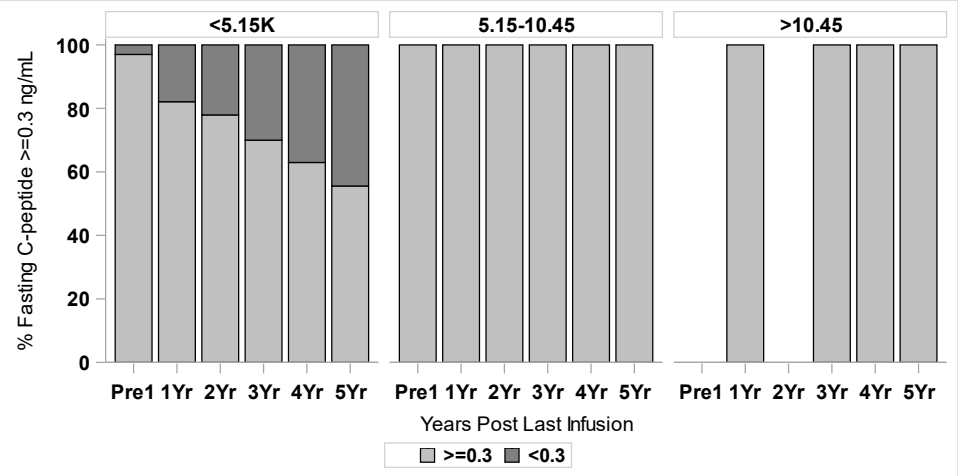
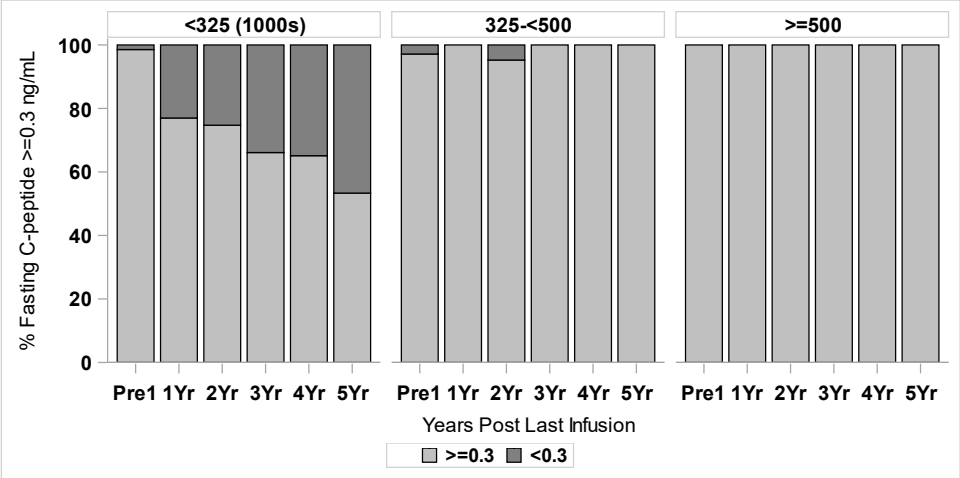


Exhibit 5-2B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Fasting C-peptide>=0.3 ng/mL Post Last Infusion among Recipients Aged 35 Years and Older

Islets IEQs infused (p=<.0001)



Density gradient (p=0.0022)

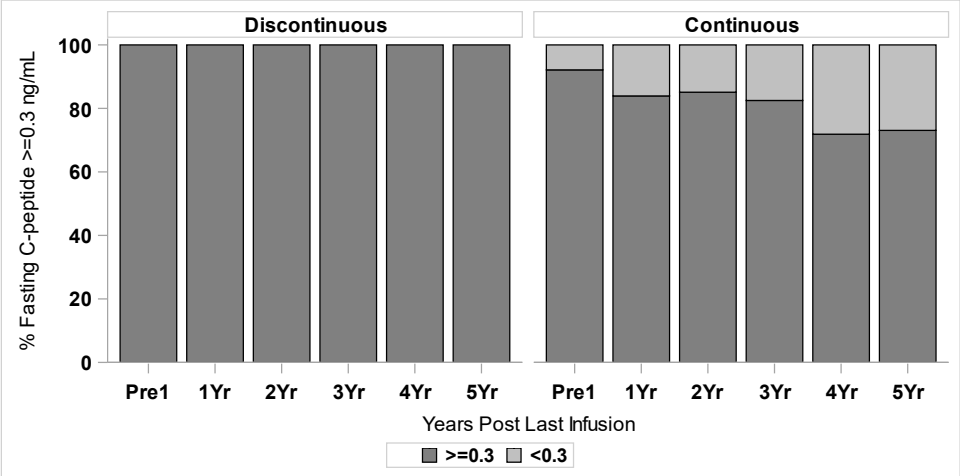
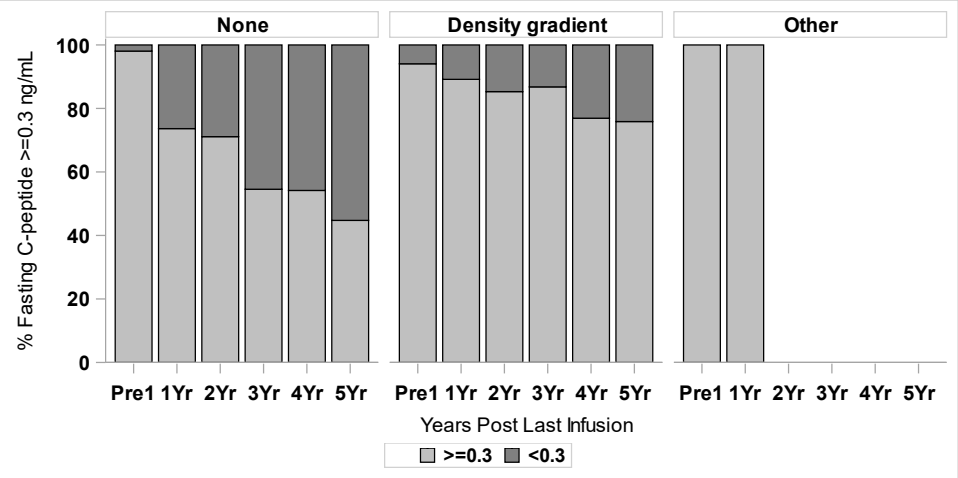
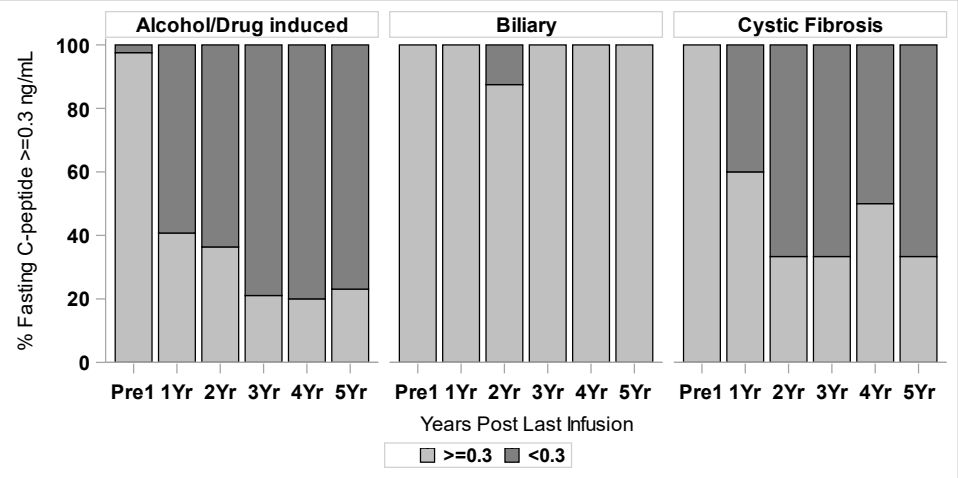


Exhibit 5-2B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Fasting C-peptide>=0.3 ng/mL Post Last Infusion among Recipients Aged 35 Years and Older

Islet purification (p=<.0001)



Pancreatitis etiology (p=0.0015)



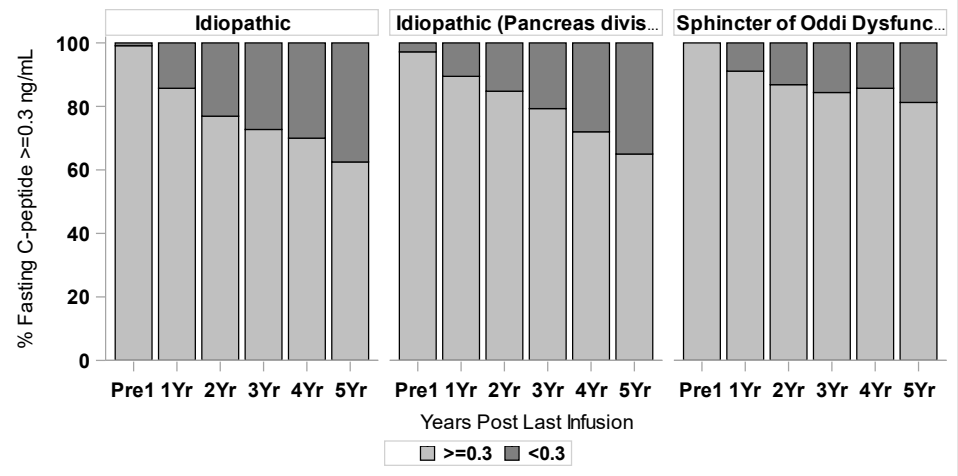
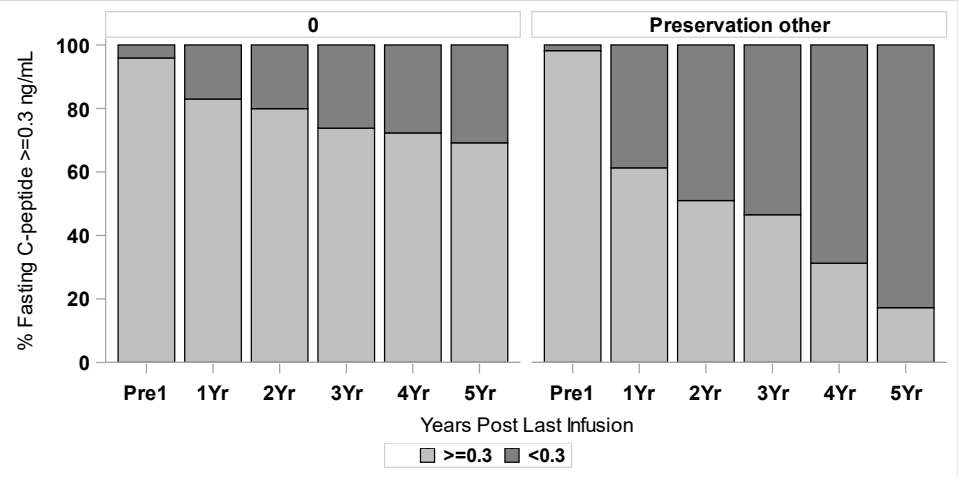
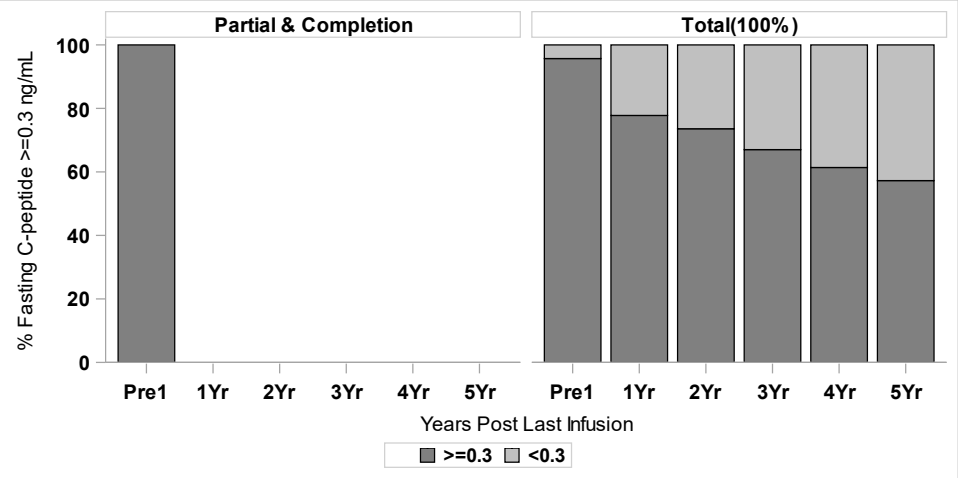


Exhibit 5-2B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Fasting C-peptide>=0.3 ng/mL Post Last Infusion among Recipients Aged 35 Years and Older

Other preservation (p=0.0002)



Pancreatectomy type (p=<.0001)



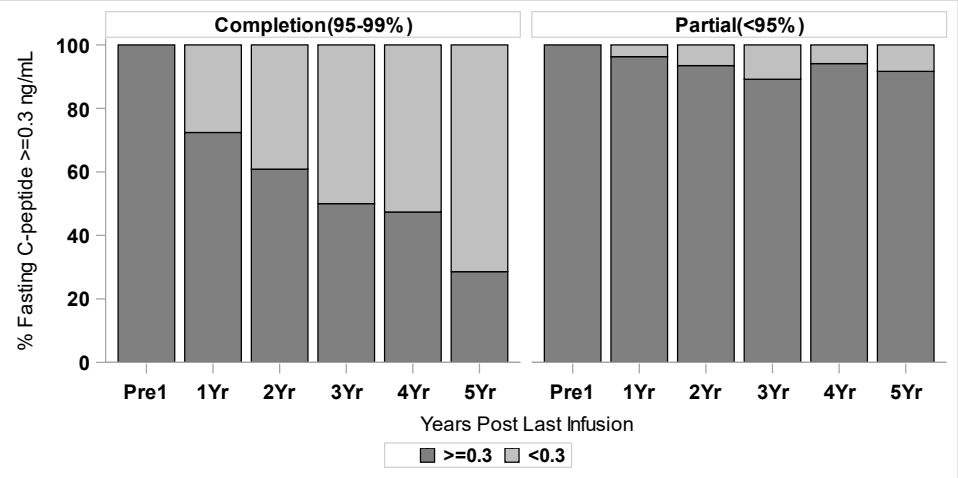
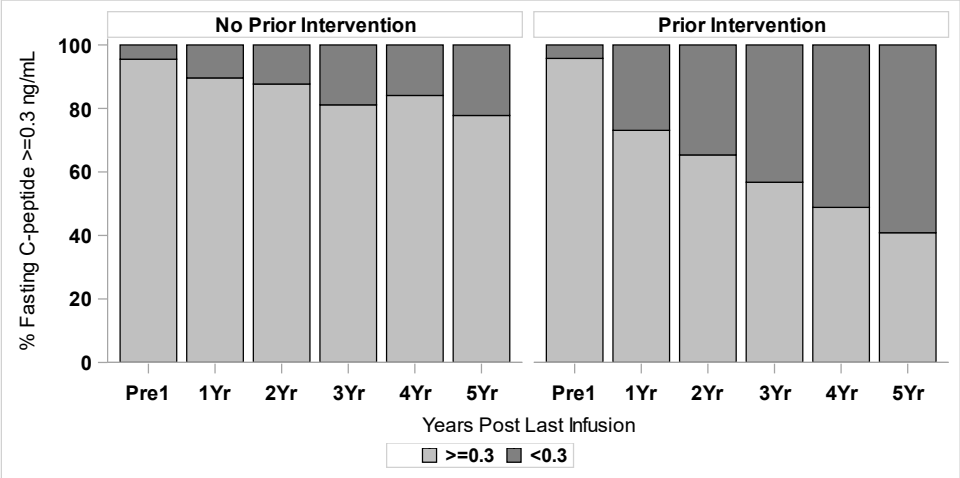


Exhibit 5-2B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Fasting C-peptide>=0.3 ng/mL Post Last Infusion among Recipients Aged 35 Years and Older

Prior Intervention (p=<.0001)



Islets IEQs/particle ratio (p=0.0058)

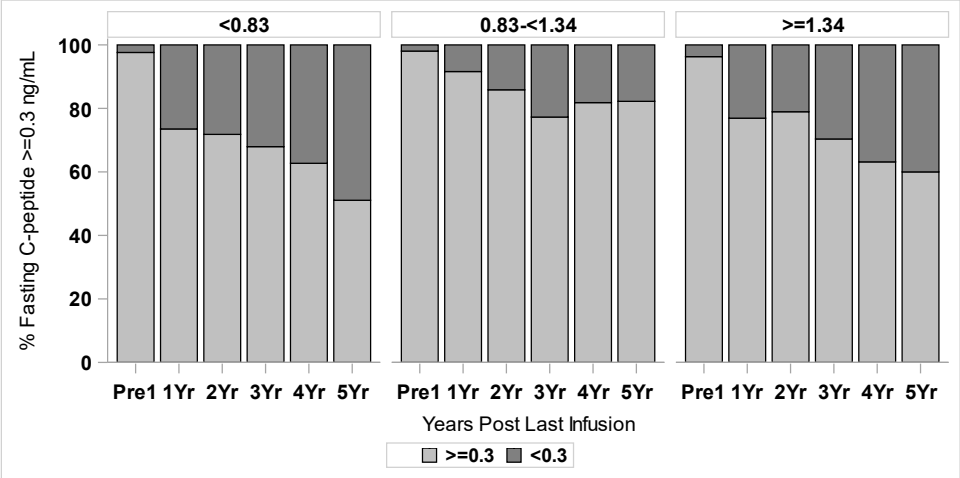
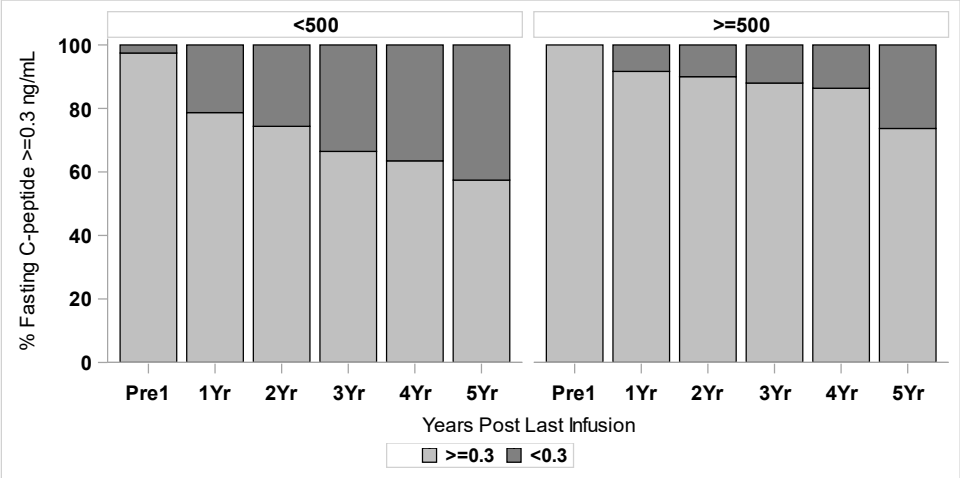


Exhibit 5-2B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Fasting C-peptide>=0.3 ng/mL Post Last Infusion among Recipients Aged 35 Years and Older

Islets particle count (p=0.0039)



Indication: Trauma (0-No 1-Yes) (p=<.0001)

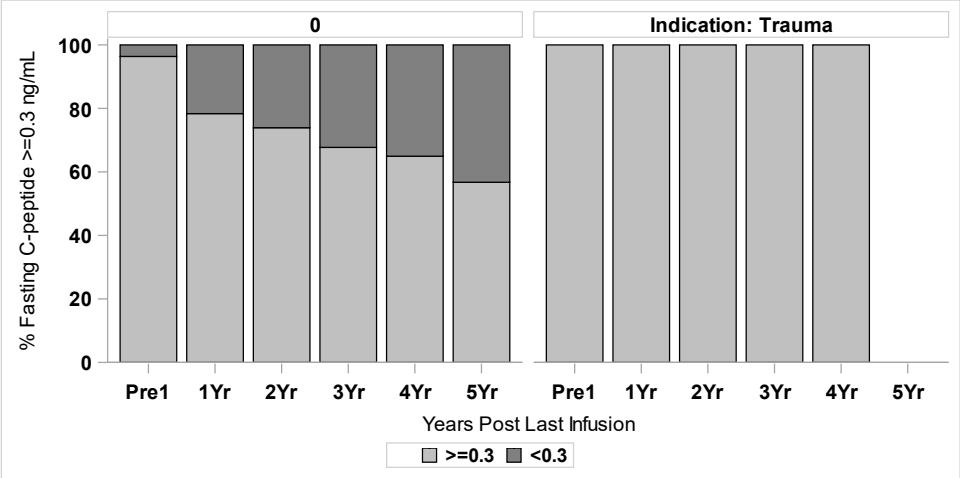


Exhibit 5-2B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Fasting C-peptide>=0.3 ng/mL Post Last Infusion among Recipients Aged 35 Years and Older

Indication: Tumors (0-No 1-Yes) (p=<.0001)

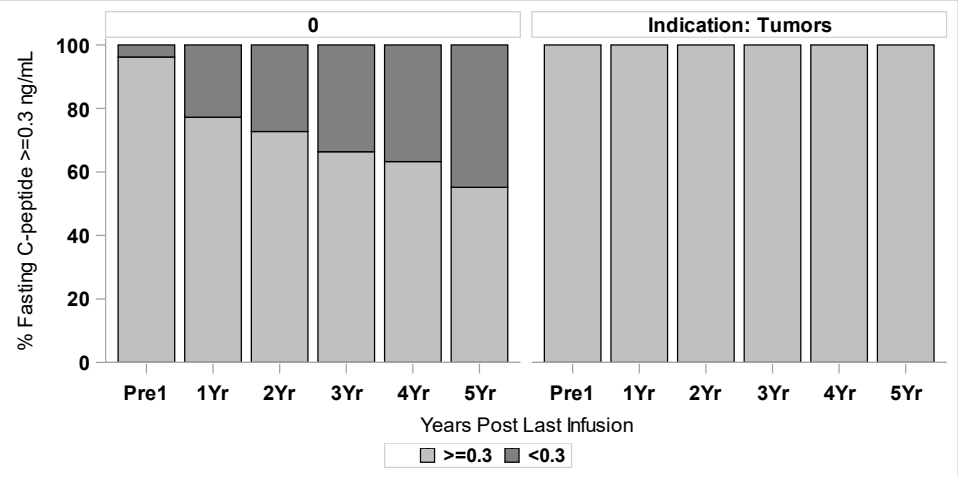
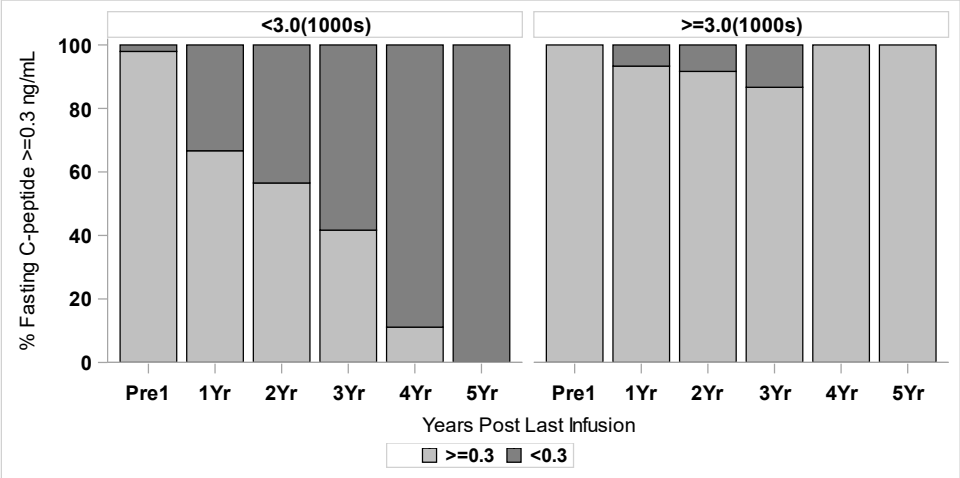


Exhibit 5-2C
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Fasting C-peptide>=0.3 ng/mL Post Last Infusion among Recipients Aged 18 to 35 Years

IEQs/kg (p=0.0005)



Baseline creatinine (p=0.0002)

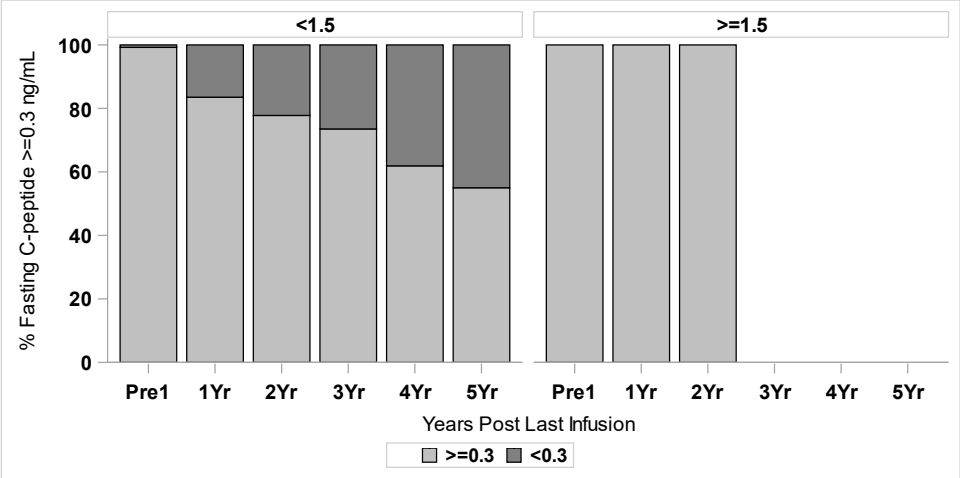
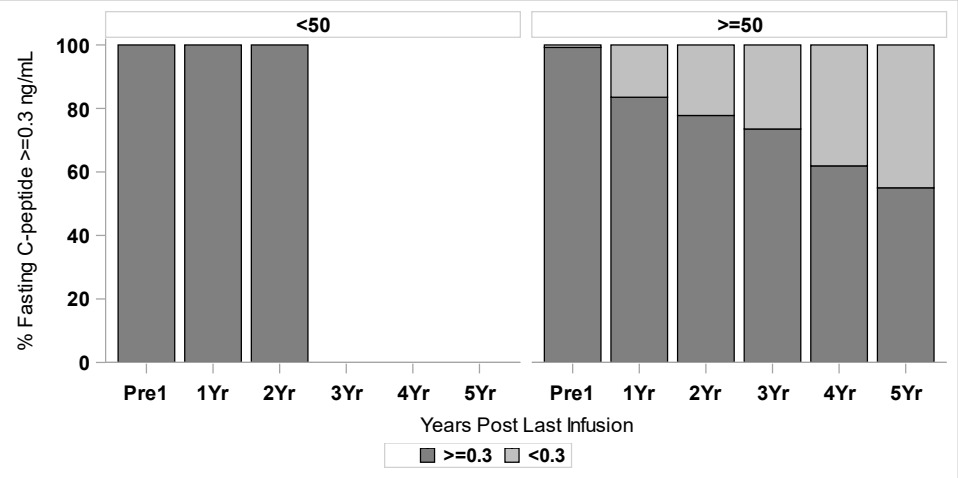


Exhibit 5-2C
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Fasting C-peptide>=0.3 ng/mL Post Last Infusion among Recipients Aged 18 to 35 Years

Baseline CKD GFR (p=0.0002)



Baseline Triglycerides (p=0.0003)

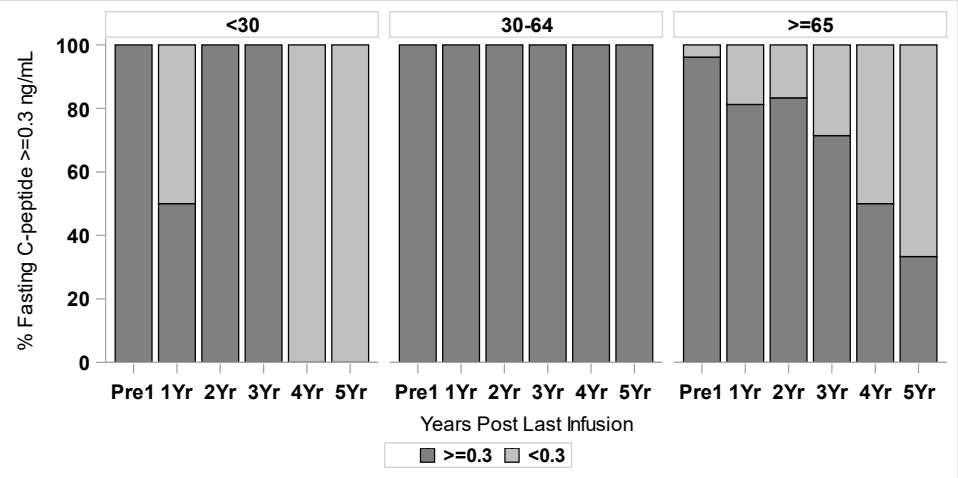
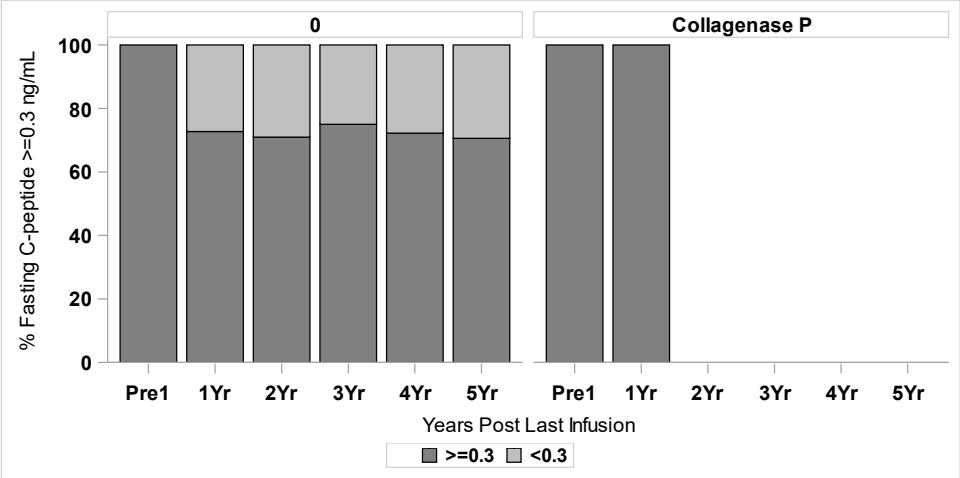
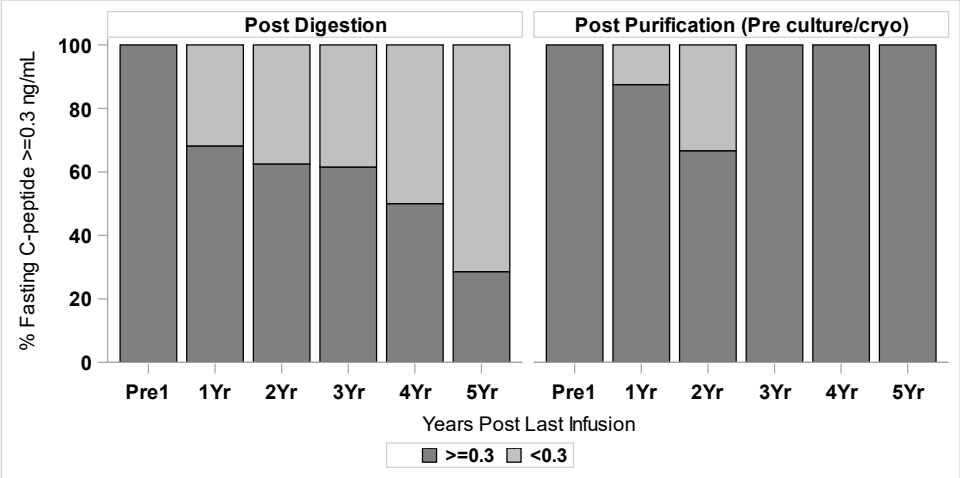


Exhibit 5-2C
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Fasting C-peptide>=0.3 ng/mL Post Last Infusion among Recipients Aged 18 to 35 Years

Collagenase P (p=0.0006)



Time of IEQ count (p=0.0095)



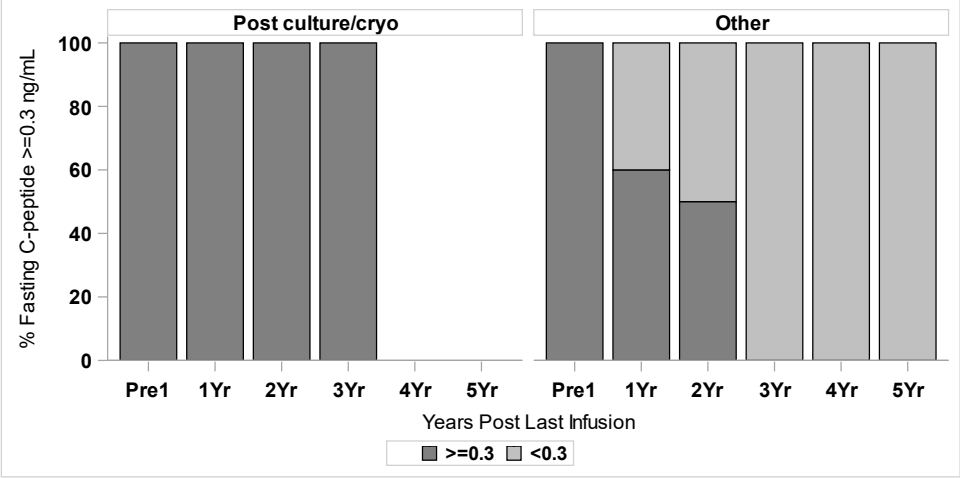
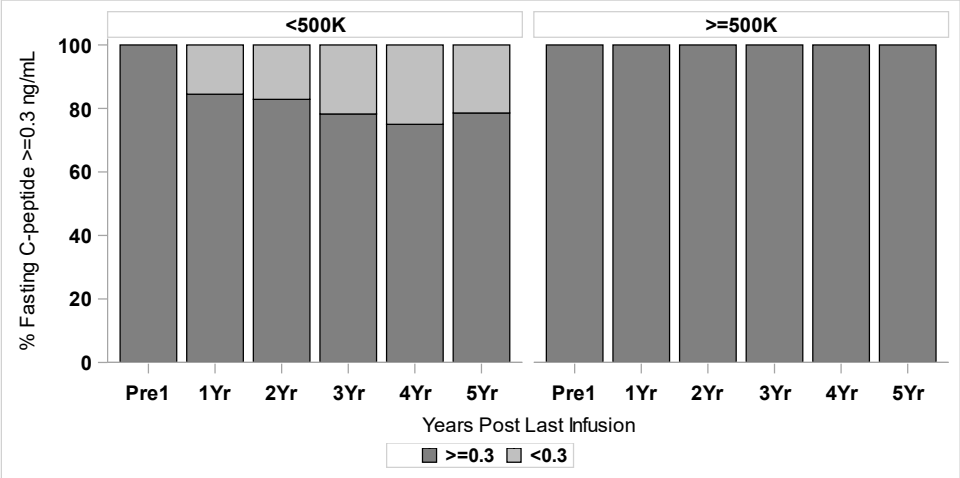


Exhibit 5-2C
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Fasting C-peptide>=0.3 ng/mL Post Last Infusion among Recipients Aged 18 to 35 Years

Islets IEQs all infusions (p=0.0092)



Preservation solution used (0-No 1-Yes) (p=0.0025)

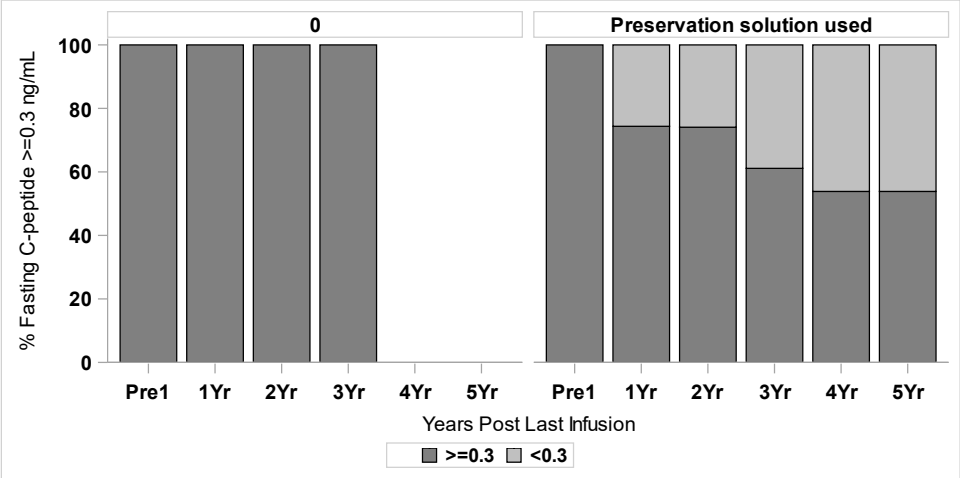
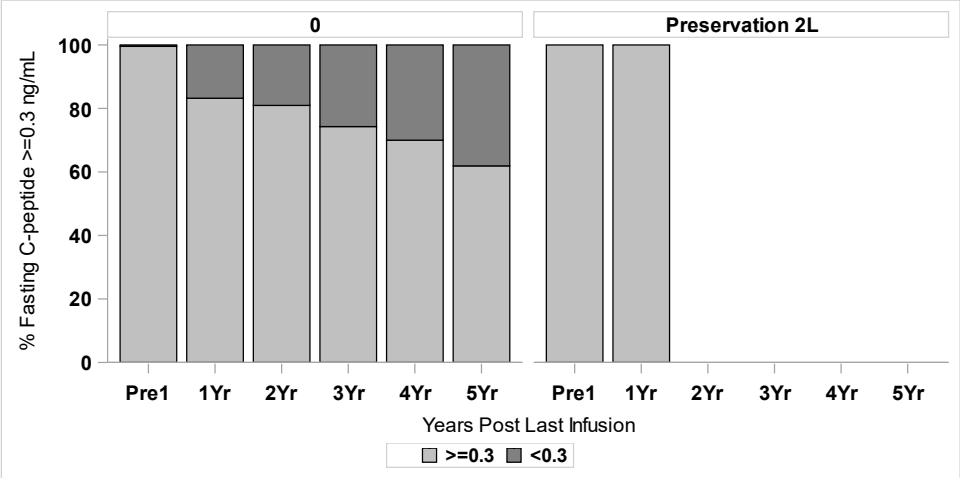


Exhibit 5-2C
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Fasting C-peptide>=0.3 ng/mL Post Last Infusion among Recipients Aged 18 to 35 Years

2L preservation (p=<.0001)



HTK preservation (p=<.0001)

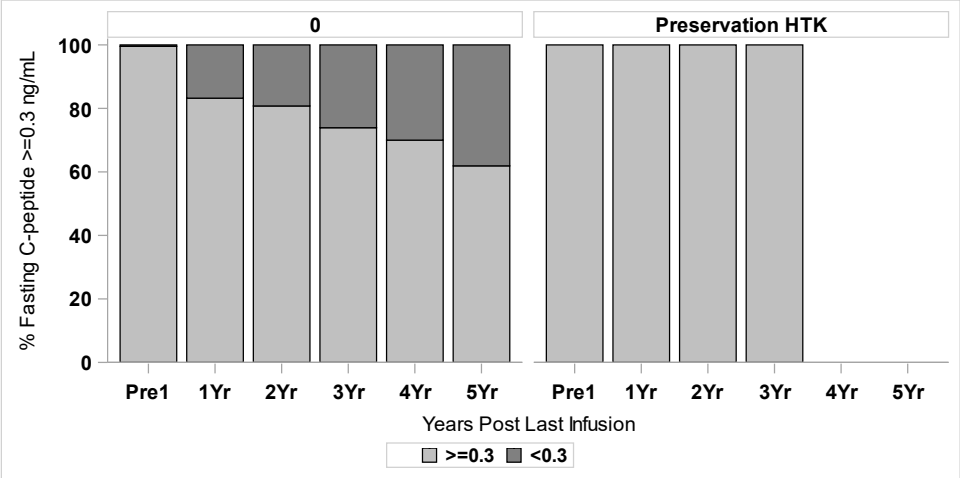
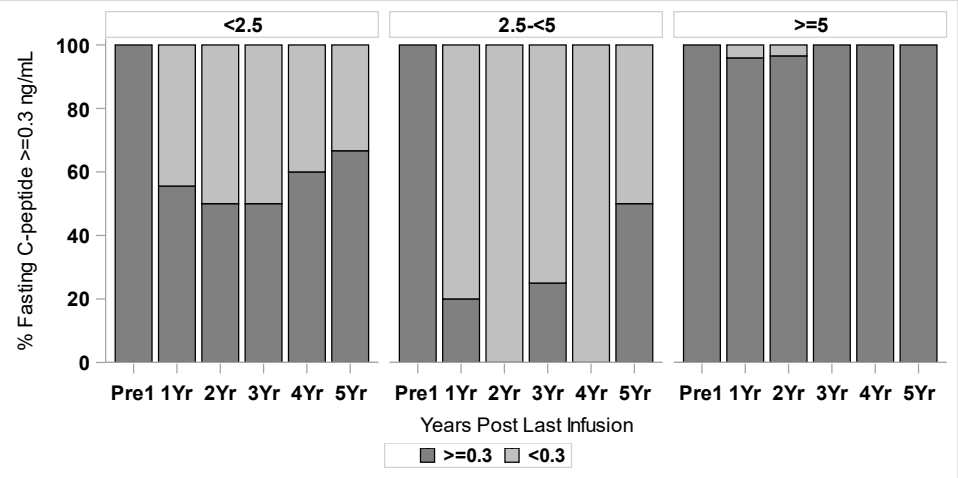


Exhibit 5-2C
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Fasting C-peptide>=0.3 ng/mL Post Last Infusion among Recipients Aged 18 to 35 Years

Total volume all infusions (p=0.0086)



Pancreatectomy type (p=<.0001)

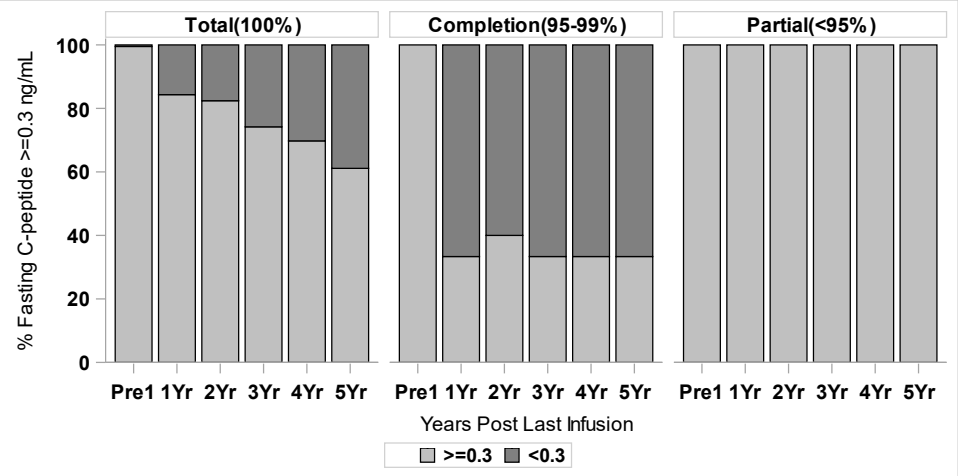
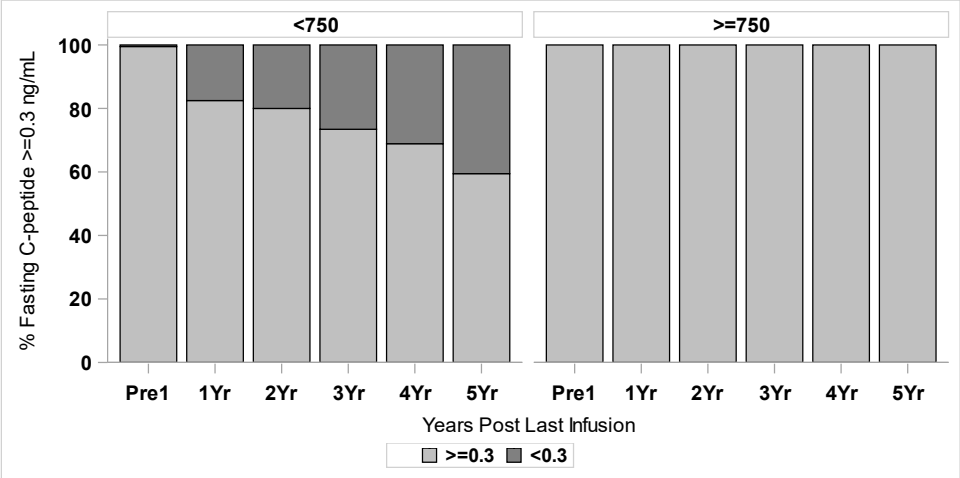


Exhibit 5-2C
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Fasting C-peptide>=0.3 ng/mL Post Last Infusion among Recipients Aged 18 to 35 Years

Islets IEQ count (p=<.0001)



Islets particle count (p=<.0001)

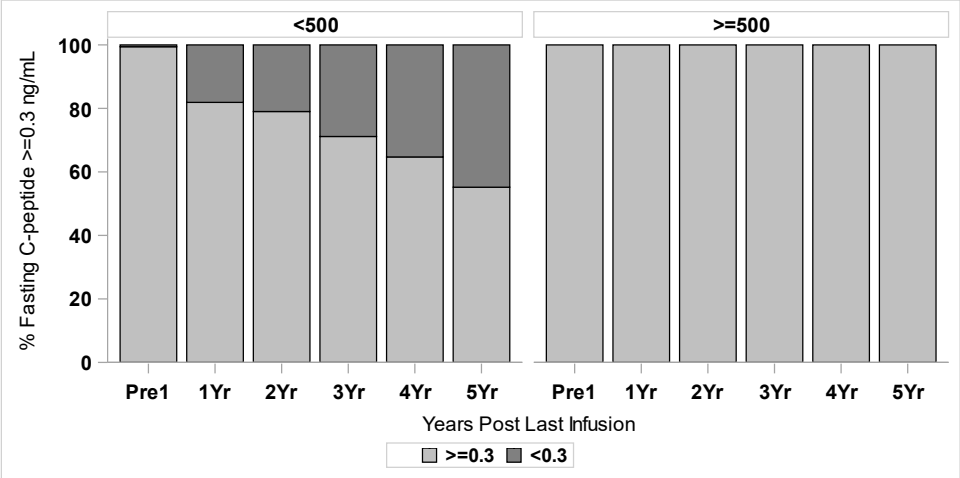
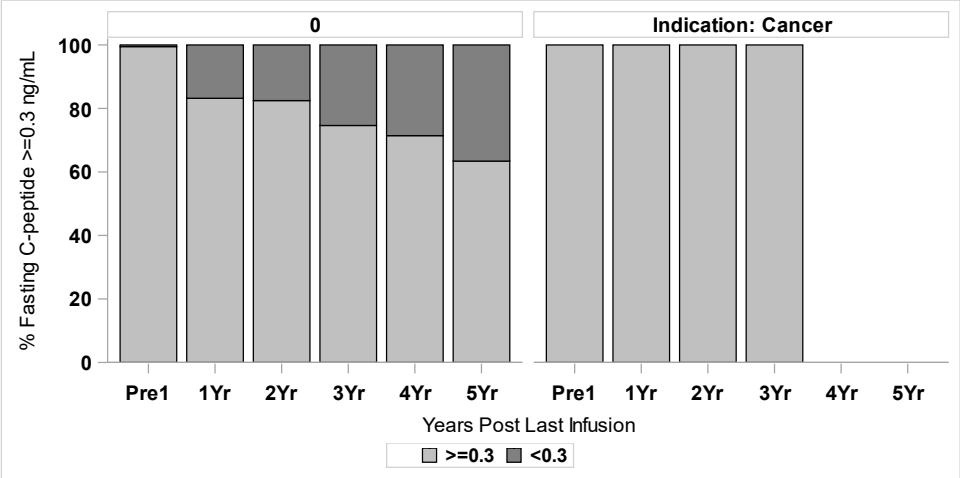


Exhibit 5-2C
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Fasting C-peptide>=0.3 ng/mL Post Last Infusion among Recipients Aged 18 to 35 Years

Indication: Cancer (0-No 1-Yes) (p=<.0001)



Indication: Pancreatitis (0-No 1-Yes) (p=0.0081)

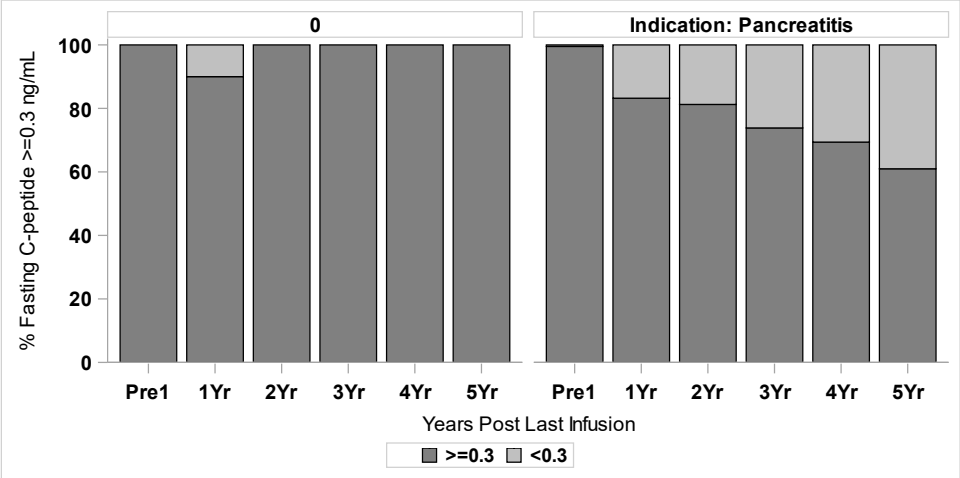
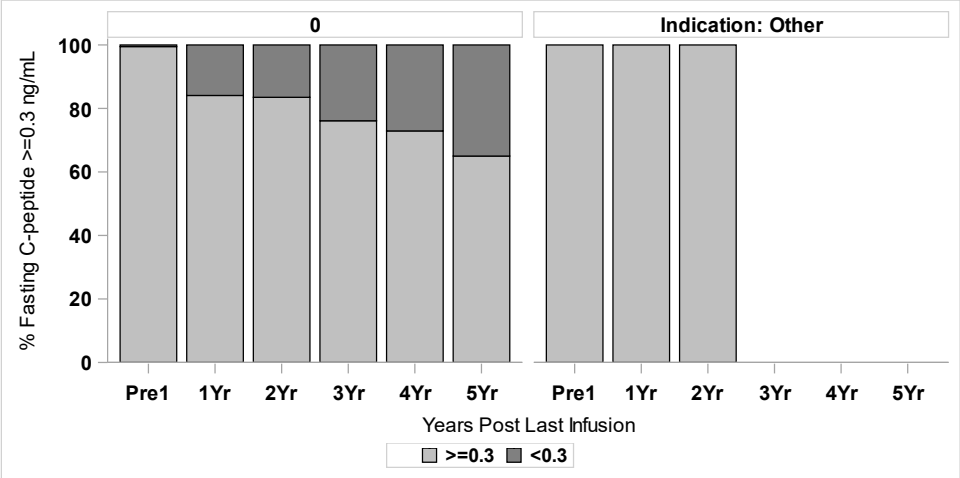


Exhibit 5-2C
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Fasting C-peptide>=0.3 ng/mL Post Last Infusion among Recipients Aged 18 to 35 Years

Indication: Other (0-No 1-Yes) (p=<.0001)



Indication: Tumors (0-No 1-Yes) (p=<.0001)

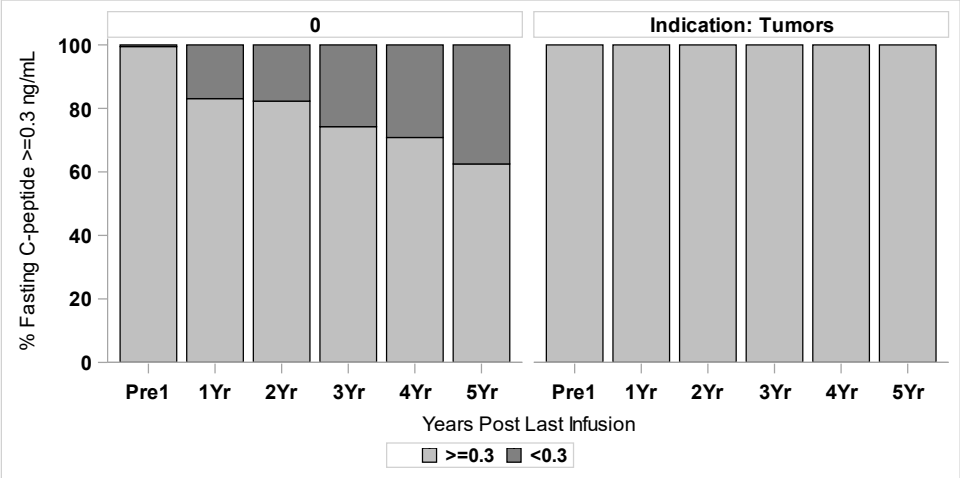


Exhibit 5-3A
Prevalence of Fasting Blood Glucose 60-140 mg/dL Post Last Infusion by Age Group (p=0.0001)

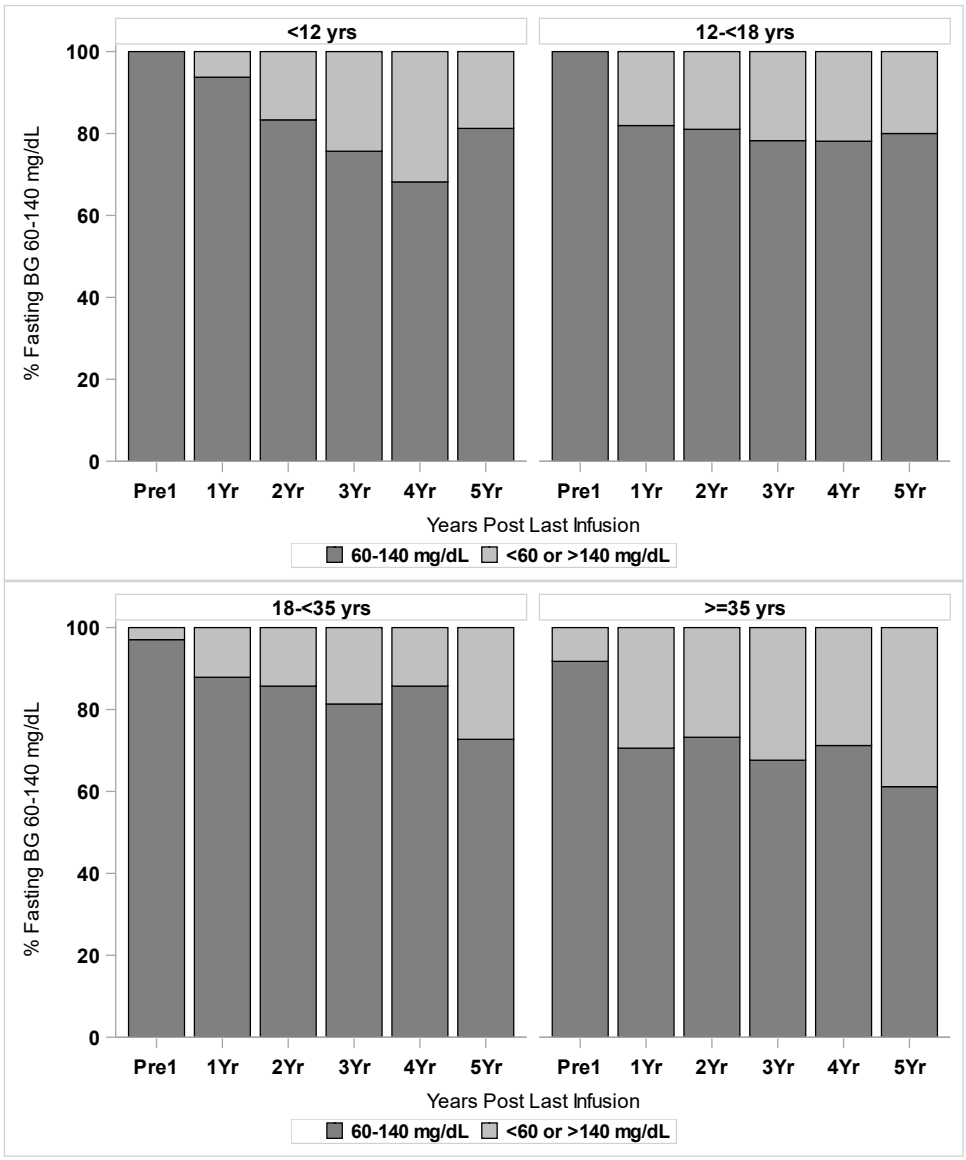
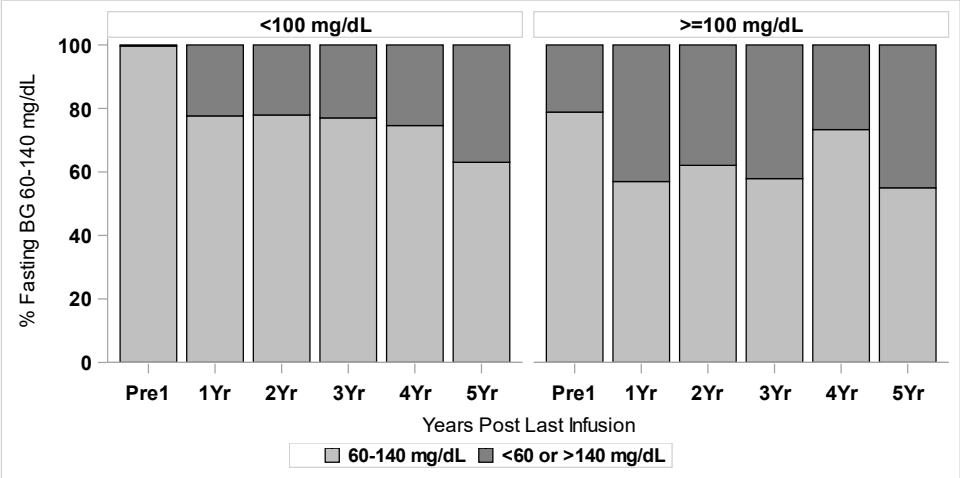


Exhibit 5-3B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Fasting Blood Glucose 60-140 mg/dL Post Last Infusion among Recipients Aged 35 Years and Older

Baseline FBG (p=0.0049)



Baseline insulin pump (p=0.0056)

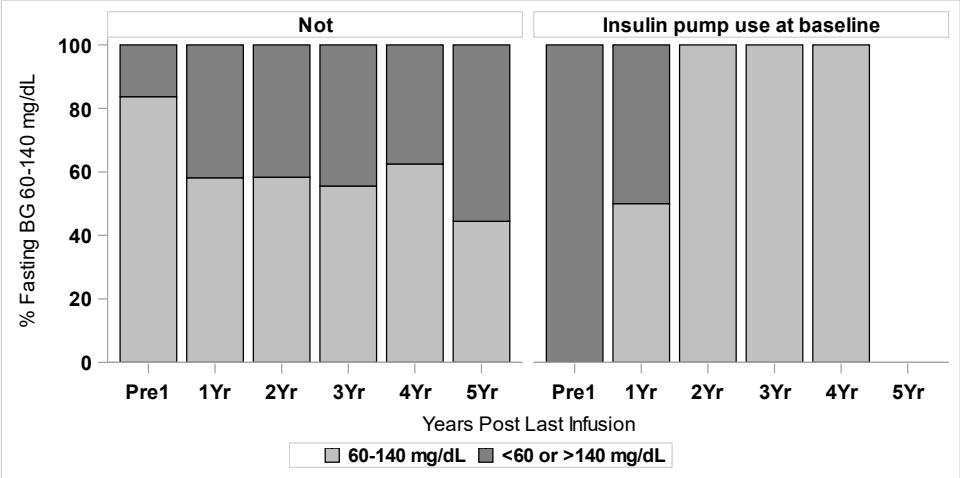
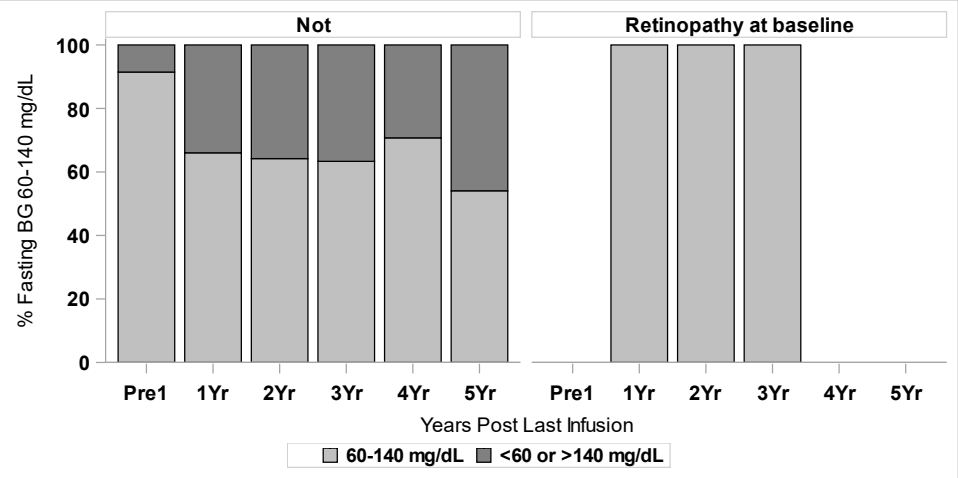


Exhibit 5-3B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Fasting Blood Glucose 60-140 mg/dL Post Last Infusion among Recipients Aged 35 Years and Older

Baseline retinopathy (p=<.0001)



Baseline Triglycerides (p=0.0087)

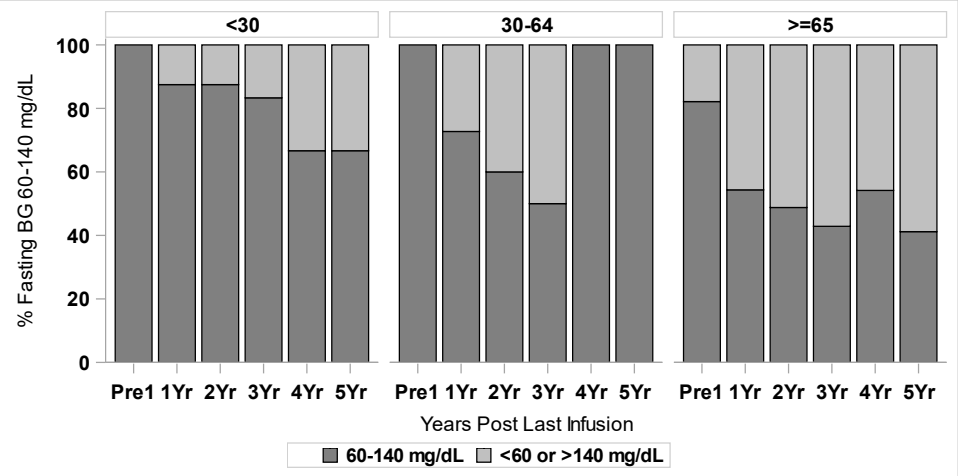
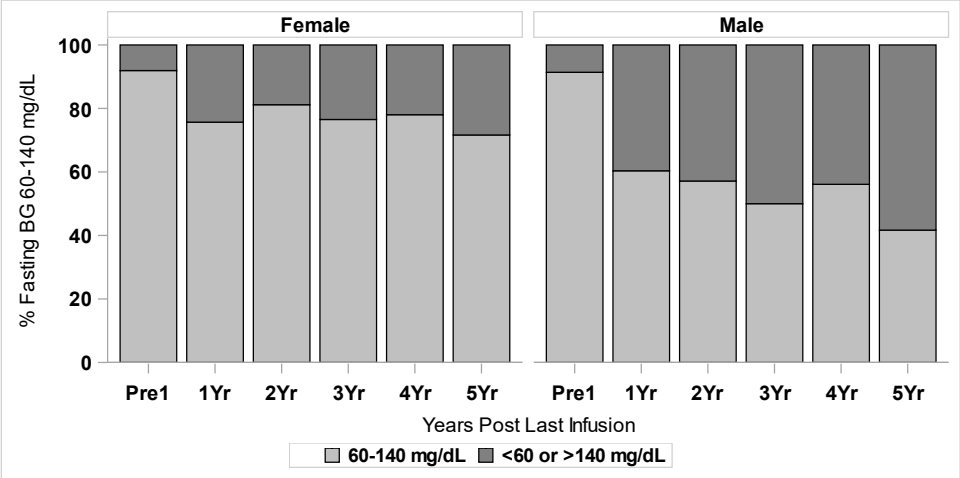
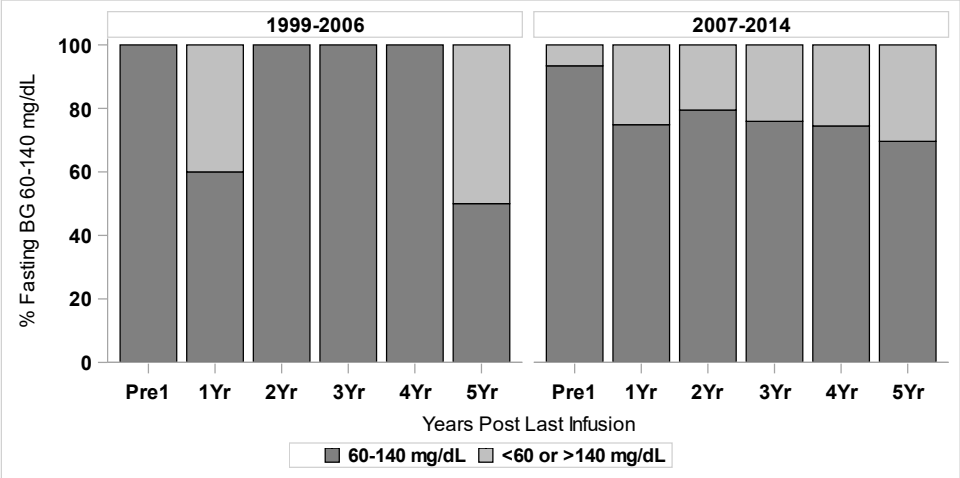


Exhibit 5-3B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Fasting Blood Glucose 60-140 mg/dL Post Last Infusion among Recipients Aged 35 Years and Older

Donor gender (p=<.0001)



Era (p=0.0006)



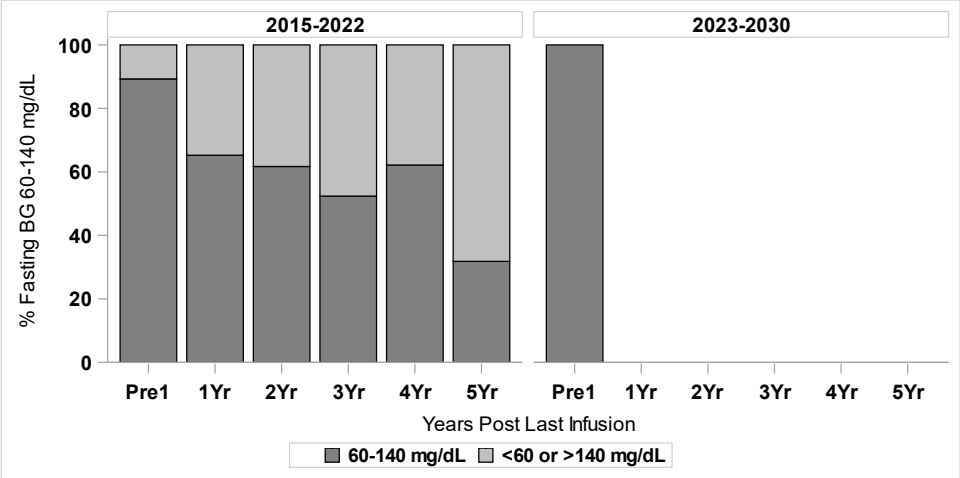
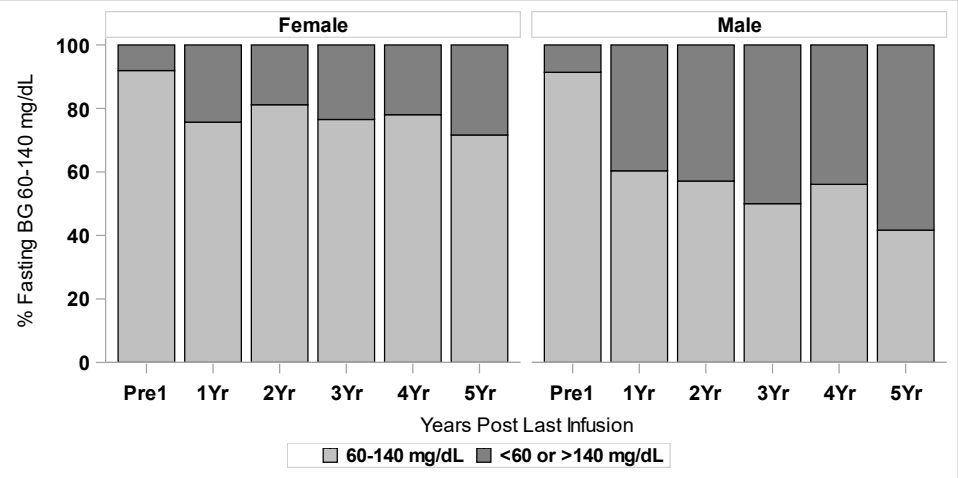
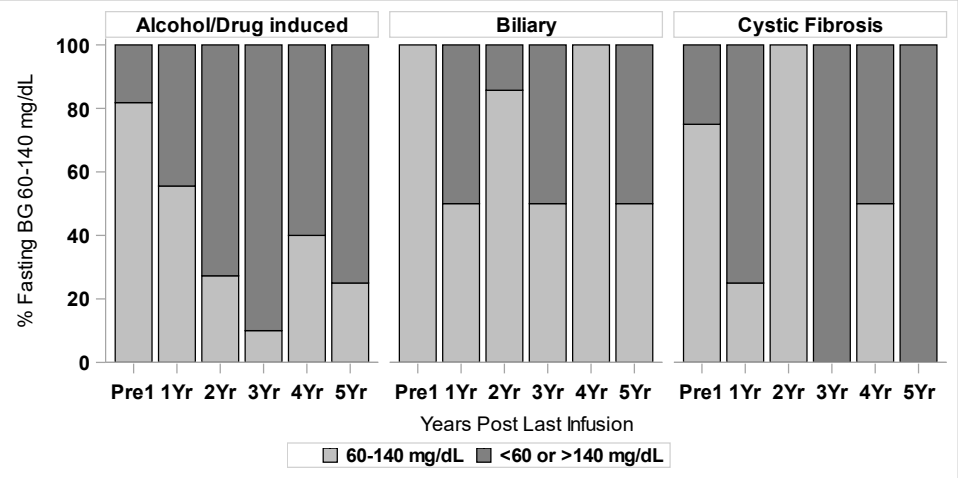


Exhibit 5-3B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Fasting Blood Glucose 60-140 mg/dL Post Last Infusion among Recipients Aged 35 Years and Older

Gender (p=<.0001)



Pancreatitis etiology (p=0.0005)



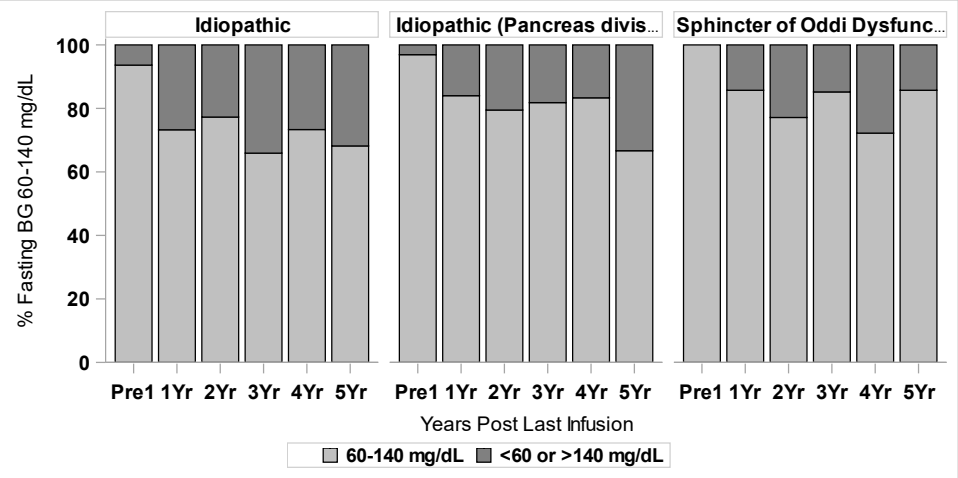
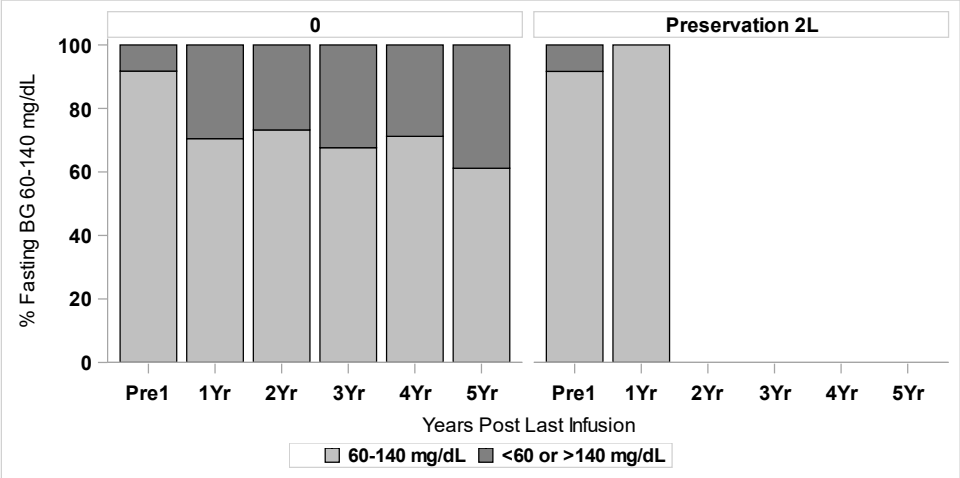


Exhibit 5-3B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Fasting Blood Glucose 60-140 mg/dL Post Last Infusion among Recipients Aged 35 Years and Older

2L preservation (p=<.0001)



Pancreatectomy type (p=<.0001)

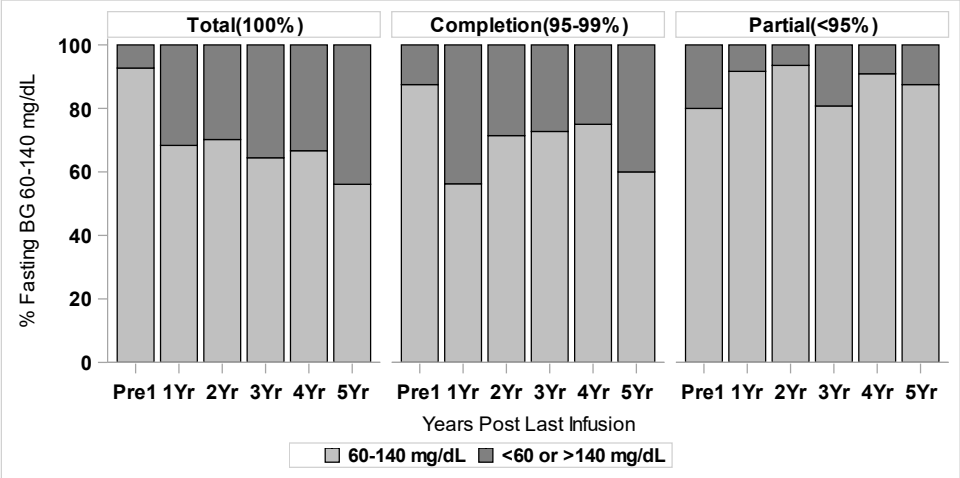
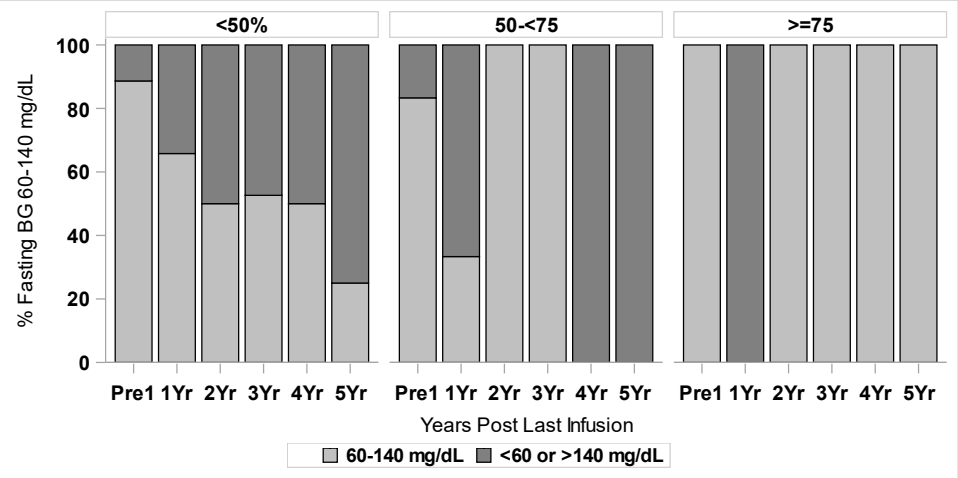


Exhibit 5-3B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Fasting Blood Glucose 60-140 mg/dL Post Last Infusion among Recipients Aged 35 Years and Older

Islets purity (p=0.0016)



Prior Frey (0-No 1-Yes) (p=<.0001)

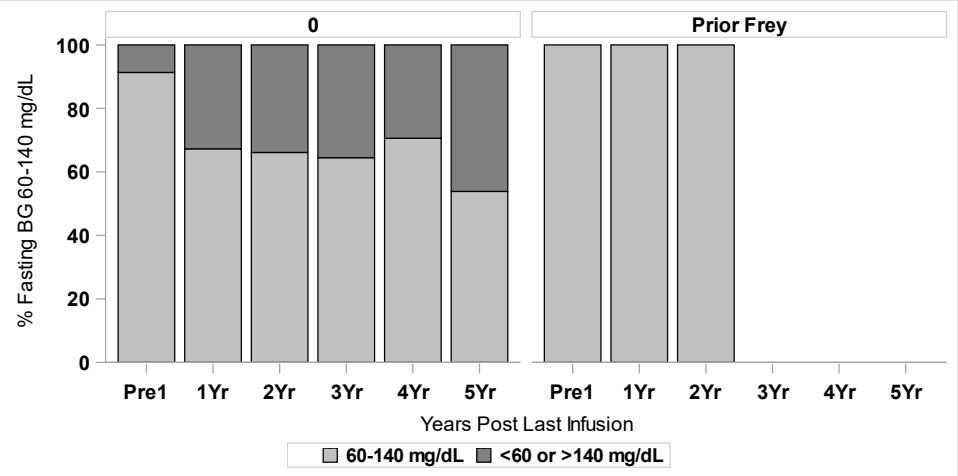


Exhibit 5-3B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Fasting Blood Glucose 60-140 mg/dL Post Last Infusion among Recipients Aged 35 Years and Older

Indication: Acute pancreatitis (0-No 1-Yes) (p=0.0008)

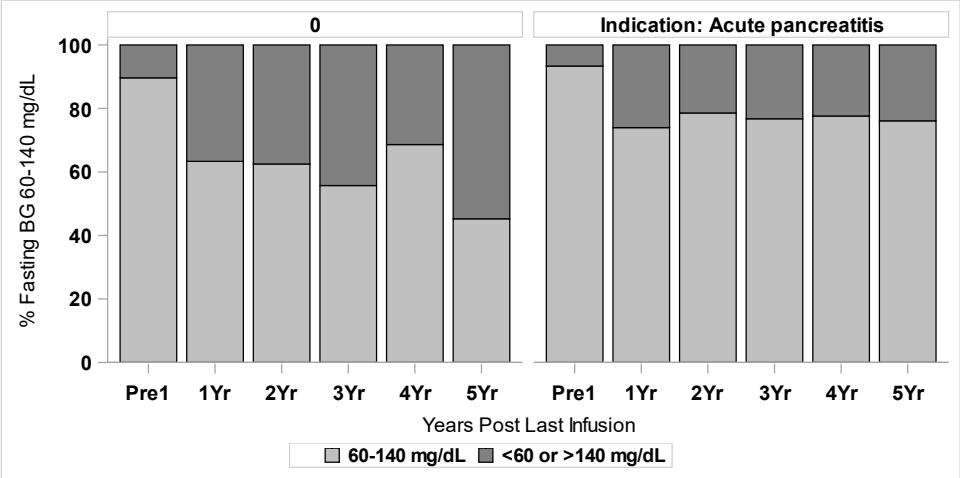


Exhibit 5-4A
Prevalence of HbA1c<7.0% Post Last Infusion by Age Group (p=0.0003)

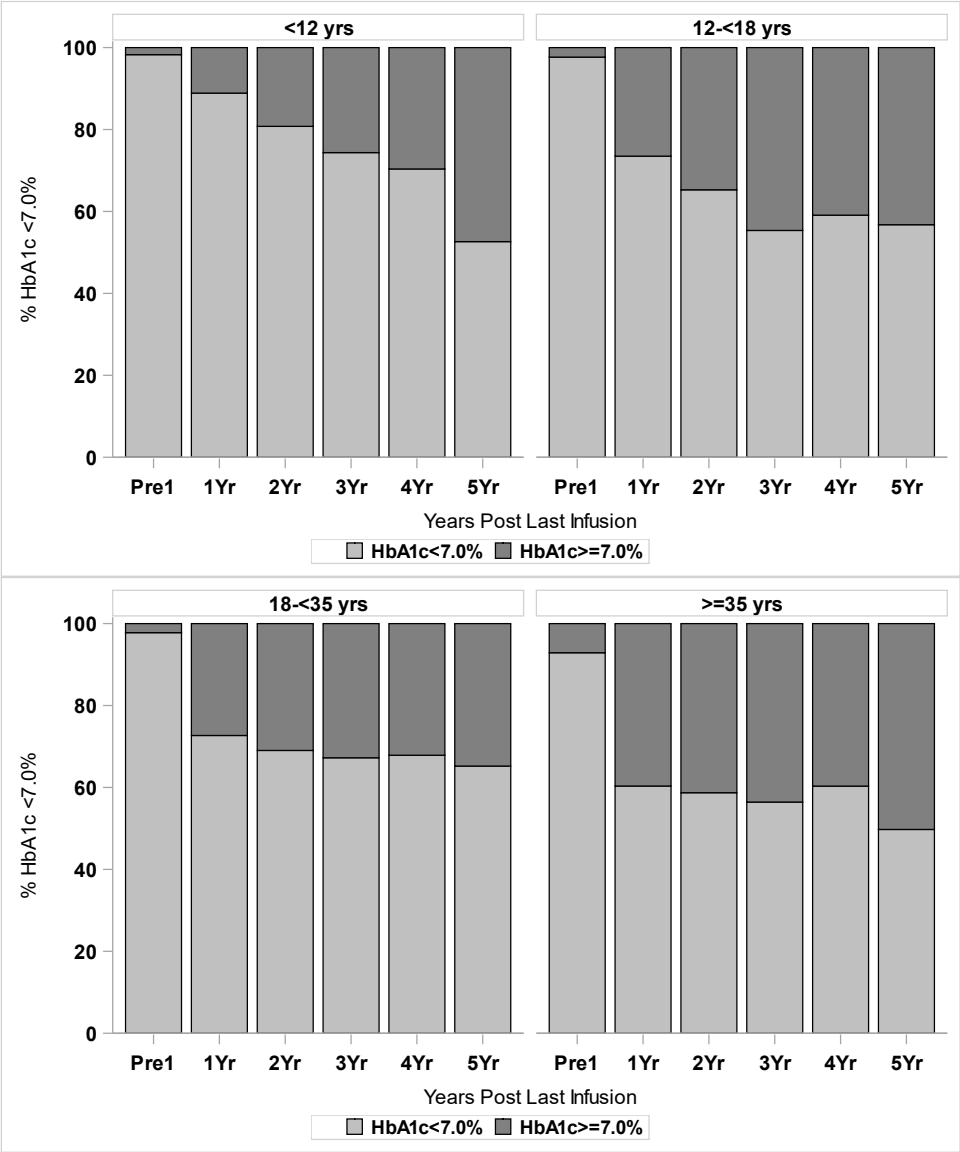
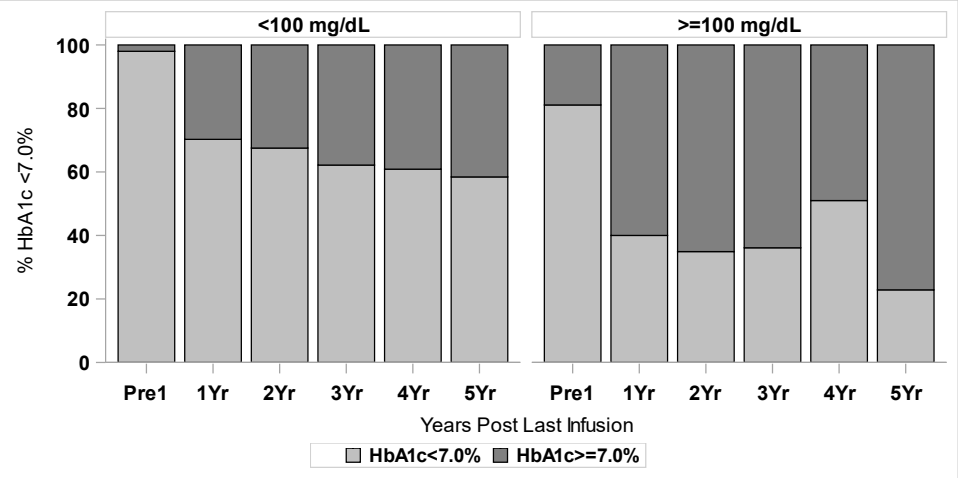


Exhibit 5-4B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of HbA1c<7.0% Post Last Infusion among Recipients Aged 35 Years and Older

Baseline FBG (p=<.0001)



Baseline HbA1c (p=0.0005)

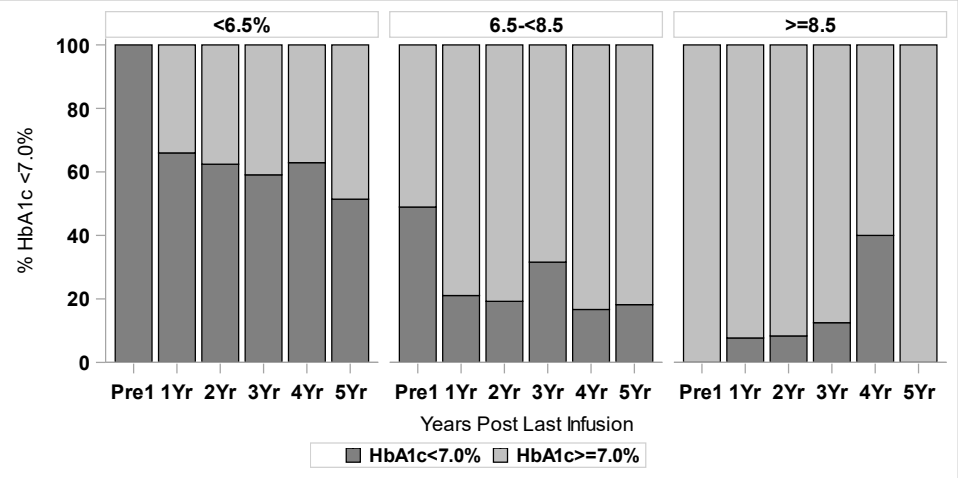
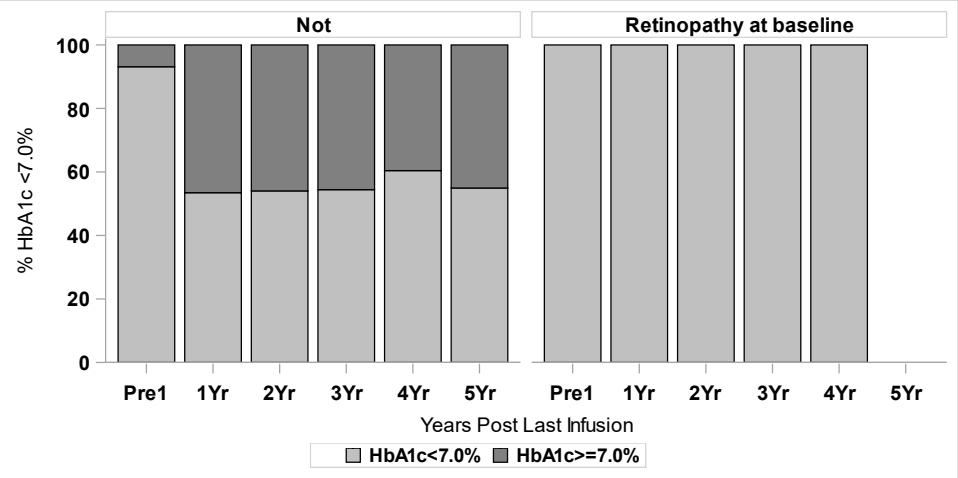


Exhibit 5-4B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of HbA1c<7.0% Post Last Infusion among Recipients Aged 35 Years and Older

Baseline retinopathy (p=<.0001)



Baseline SBP (p=0.0052)

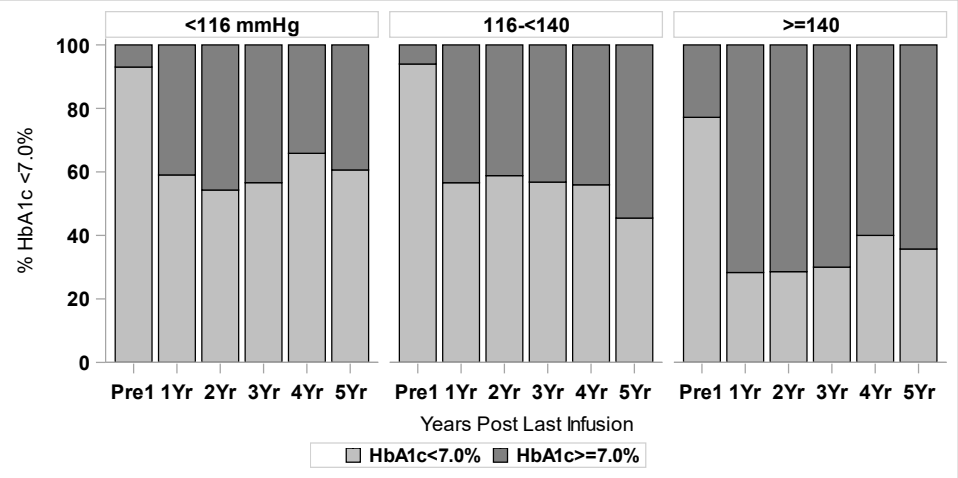
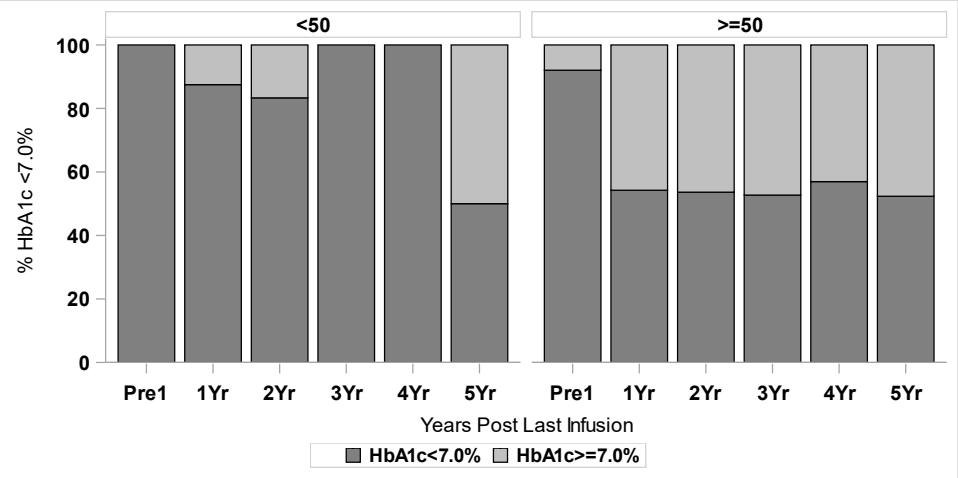


Exhibit 5-4B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of HbA1c<7.0% Post Last Infusion among Recipients Aged 35 Years and Older

Baseline CKD GFR (p=<.0001)



Collagenase P (p=<.0001)

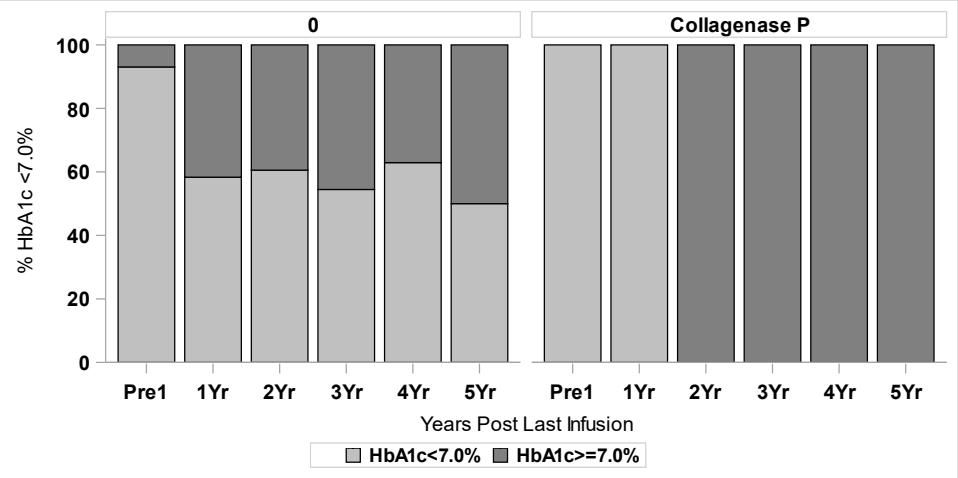
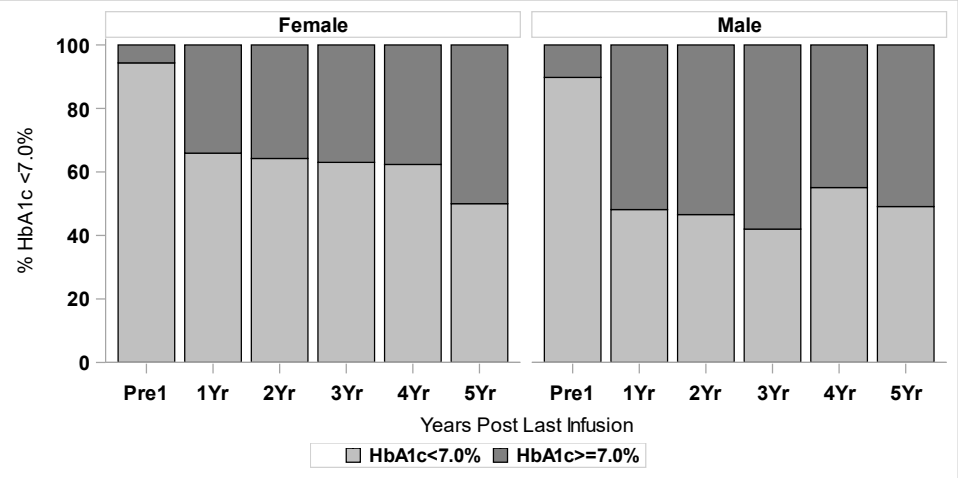
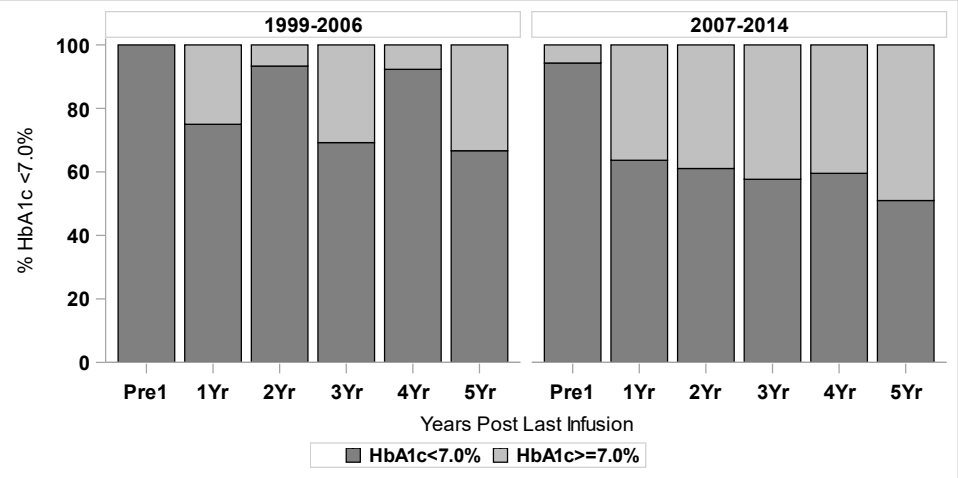


Exhibit 5-4B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of HbA1c<7.0% Post Last Infusion among Recipients Aged 35 Years and Older

Donor gender (p=0.0007)



Era (p=<.0001)



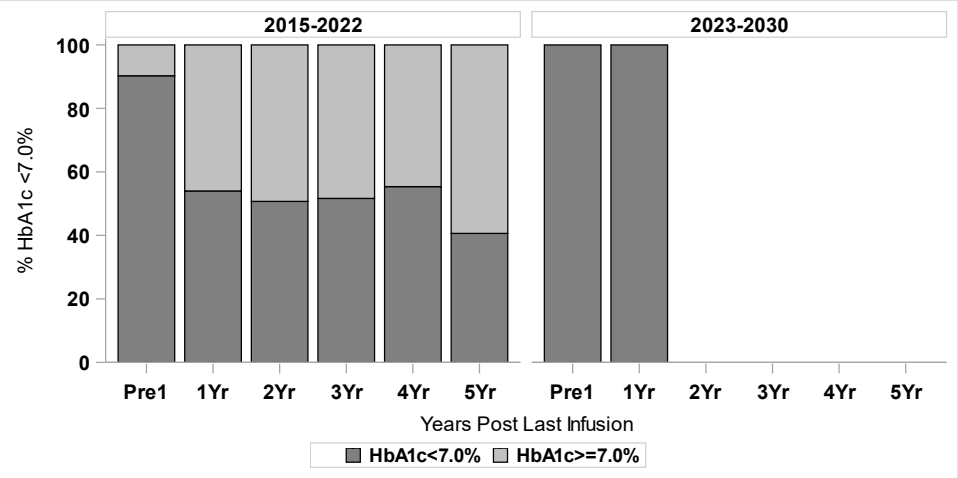
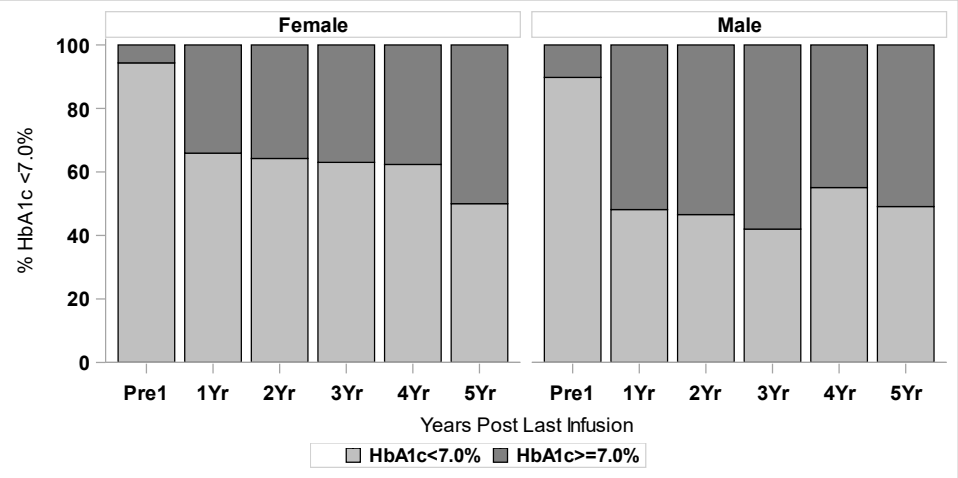


Exhibit 5-4B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of HbA1c<7.0% Post Last Infusion among Recipients Aged 35 Years and Older

Gender (p=0.0007)



Islet purification (p=0.0014)

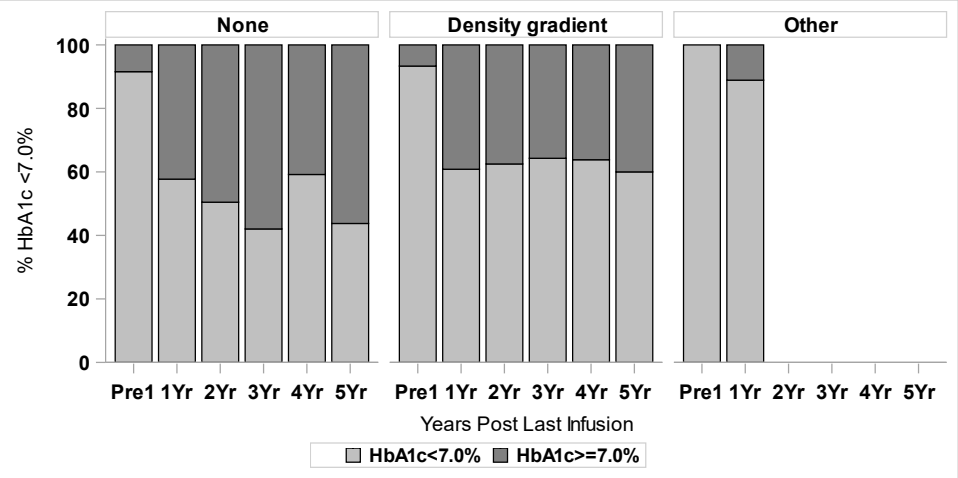
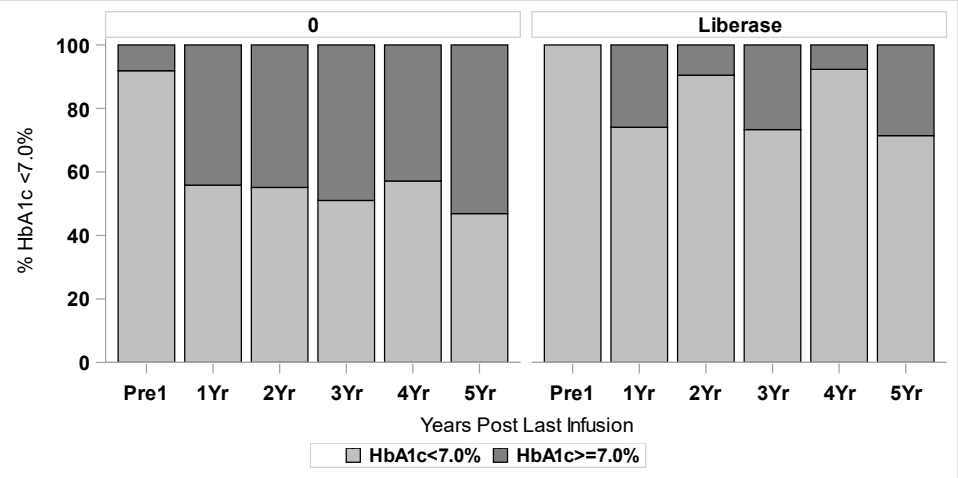
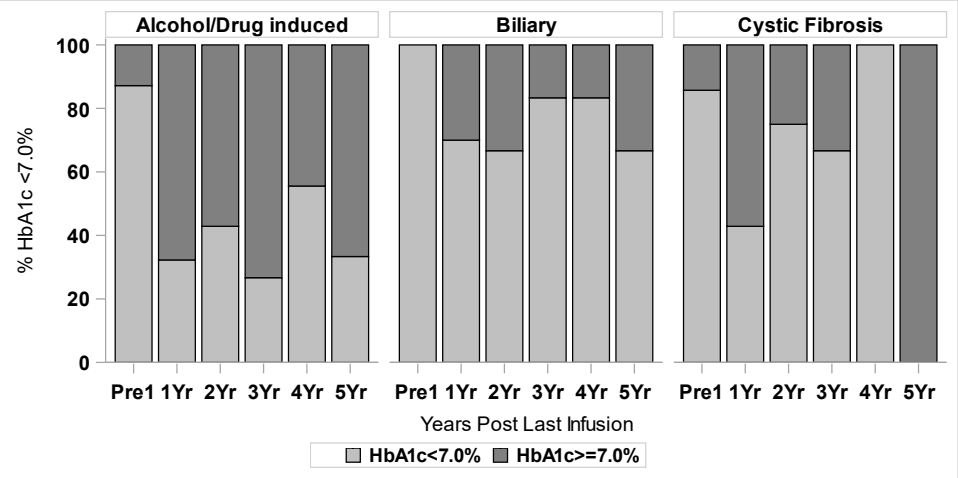


Exhibit 5-4B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of HbA1c<7.0% Post Last Infusion among Recipients Aged 35 Years and Older

Liberase (p=<.0001)



Pancreatitis etiology (p=<.0001)



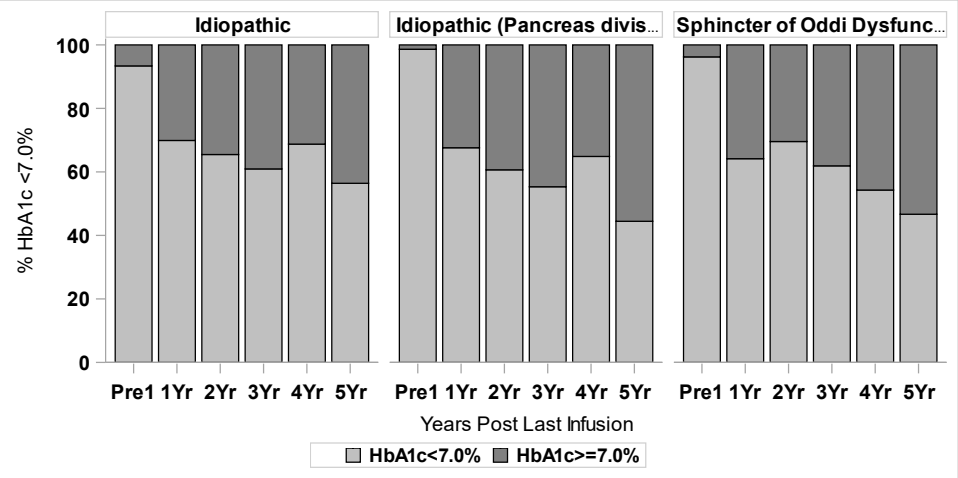
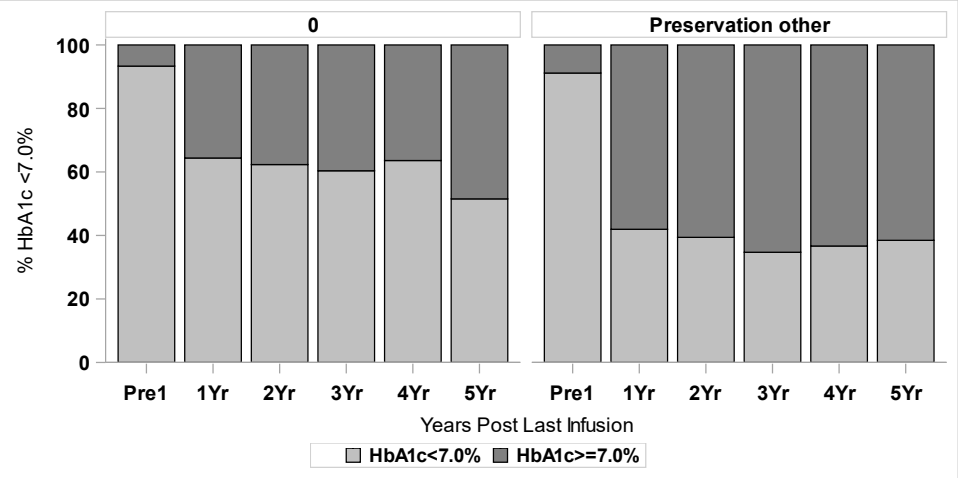


Exhibit 5-4B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of HbA1c<7.0% Post Last Infusion among Recipients Aged 35 Years and Older

Other preservation (p=0.0006)



UW preservation (p=0.0022)

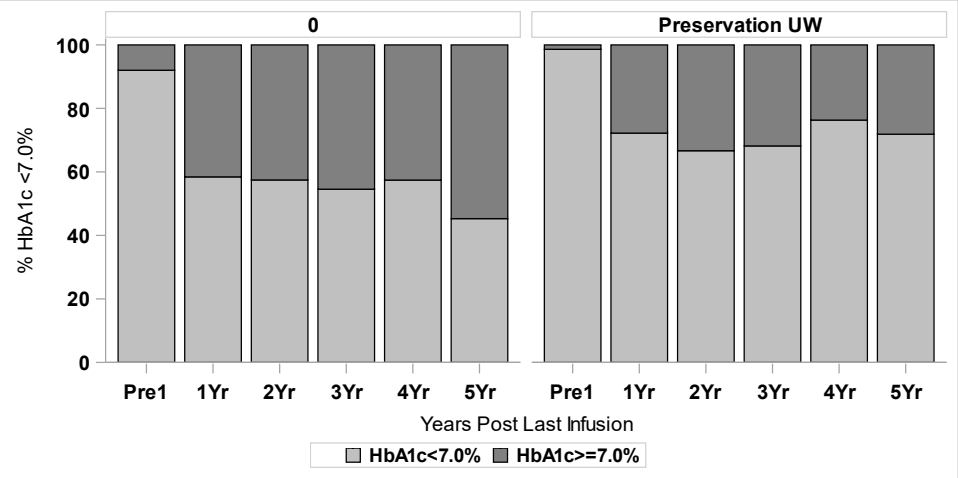
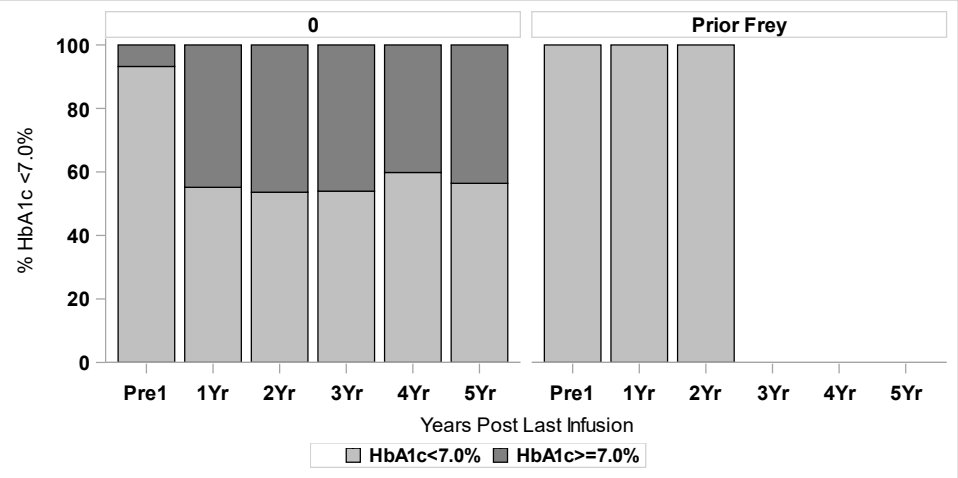


Exhibit 5-4B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of HbA1c<7.0% Post Last Infusion among Recipients Aged 35 Years and Older

Prior Frey (0-No 1-Yes) (p=<.0001)



Indication: Chronic pancreatitis (0-No 1-Yes) (p=0.0011)

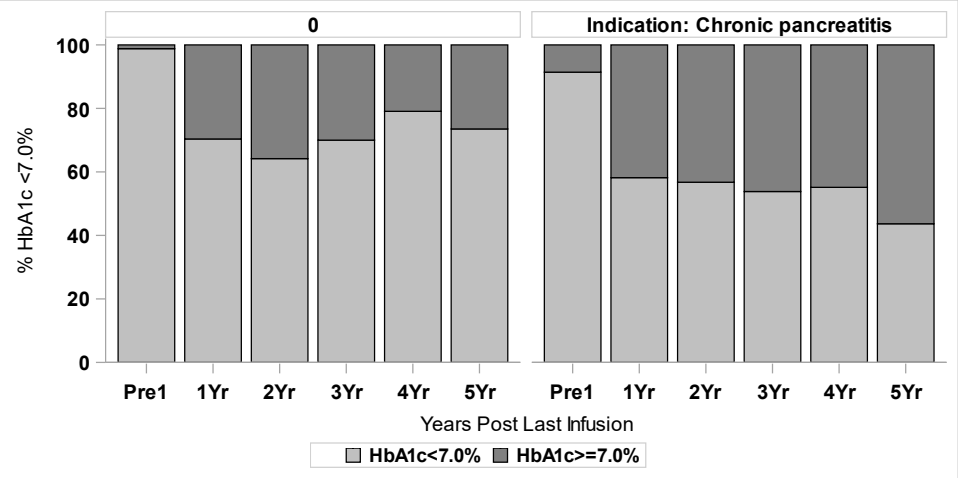


Exhibit 5-4B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of HbA1c<7.0% Post Last Infusion among Recipients Aged 35 Years and Older

Indication: Tumors (0-No 1-Yes) (p=<.0001)

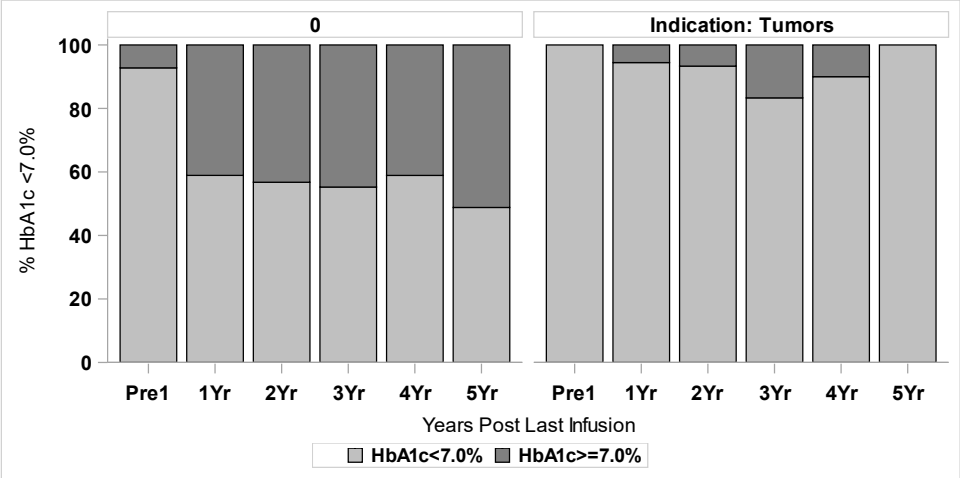
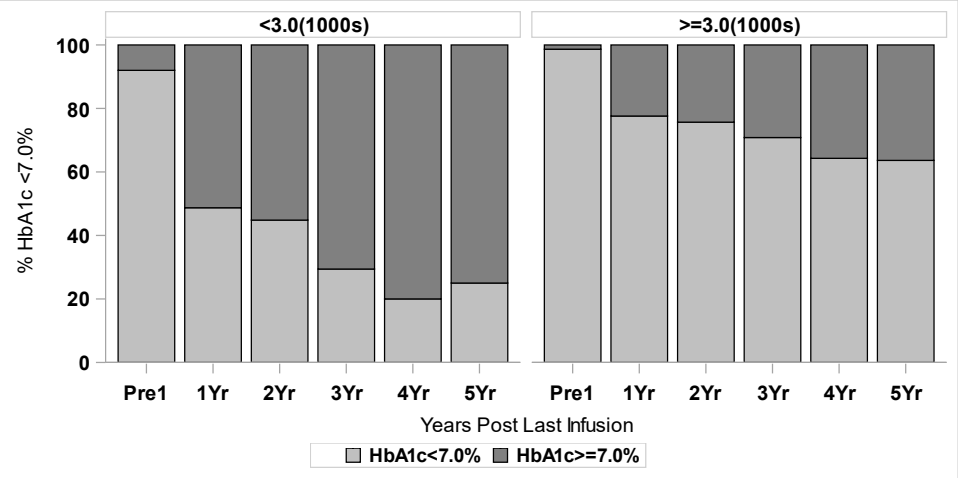


Exhibit 5-4C
Univariate Effects of Individual Variables (p<0.01) on Prevalence of HbA1c<7.0% Post Last Infusion among Recipients Aged 18 to 35 Years

IEQs/kg (p=0.0021)



IEQs (p=0.0012)

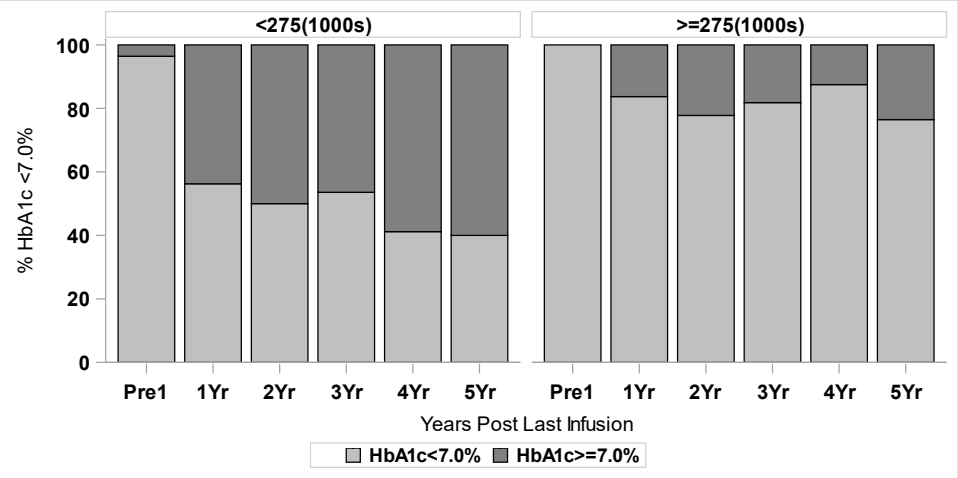
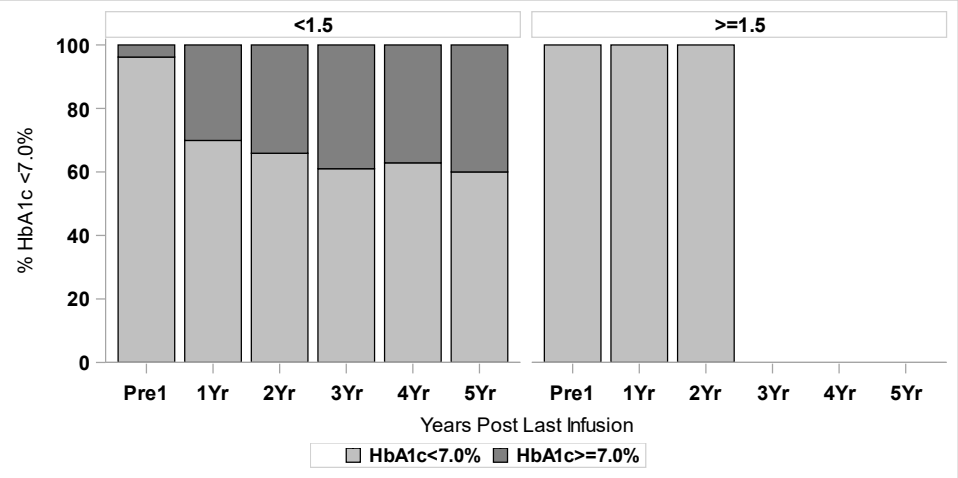


Exhibit 5-4C
Univariate Effects of Individual Variables (p<0.01) on Prevalence of HbA1c<7.0% Post Last Infusion among Recipients Aged 18 to 35 Years

Baseline creatinine (p=<.0001)



Baseline hypoglycemia (p=<.0001)

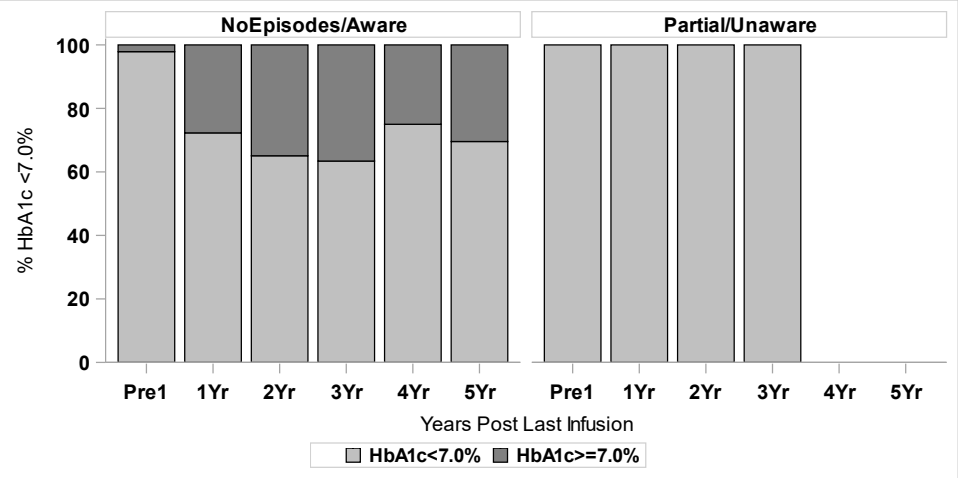
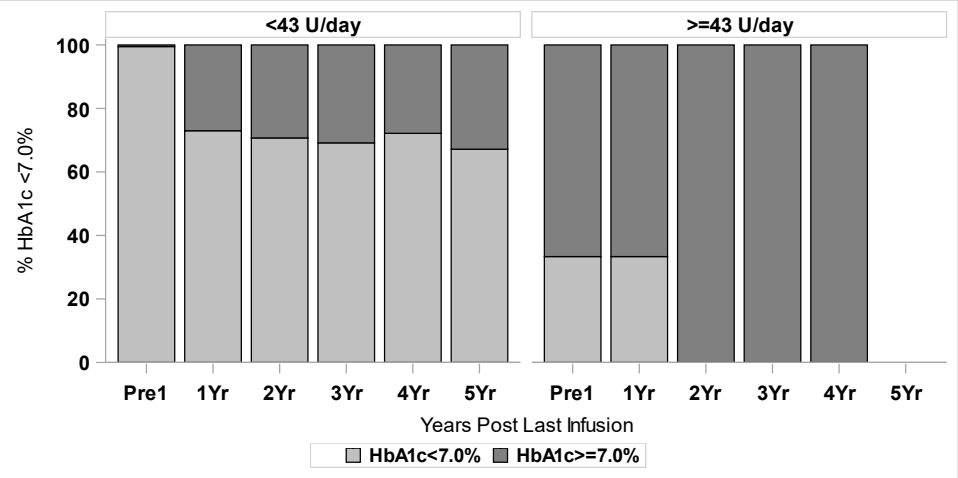


Exhibit 5-4C
Univariate Effects of Individual Variables (p<0.01) on Prevalence of HbA1c<7.0% Post Last Infusion among Recipients Aged 18 to 35 Years

Baseline insulin (U/day) (p=0.0050)



Baseline CKD GFR (p=<.0001)

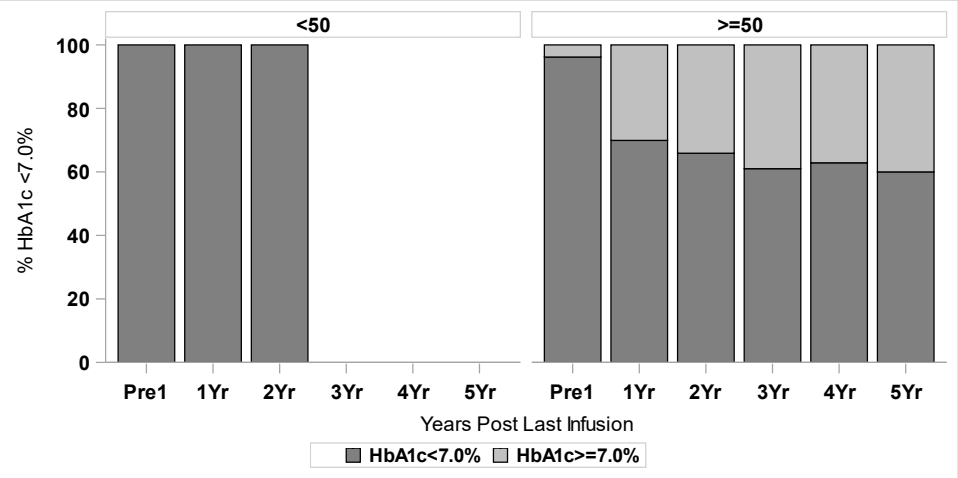
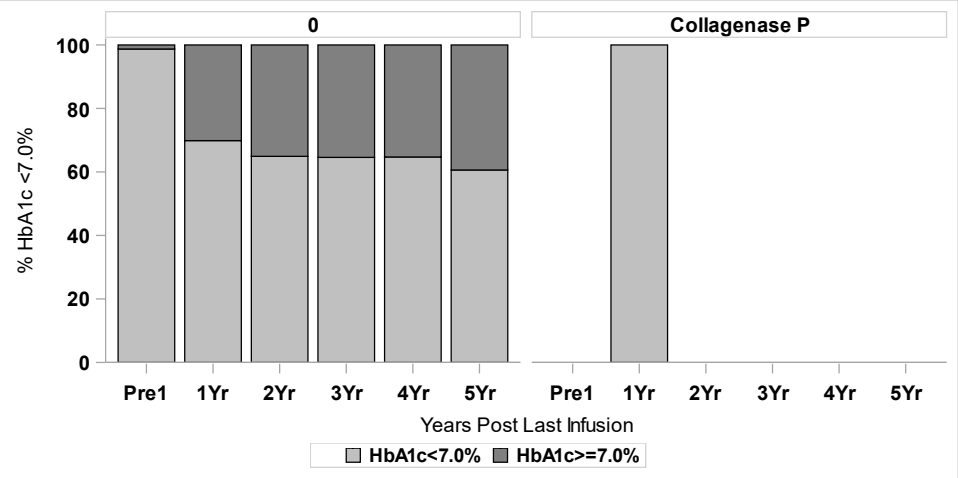


Exhibit 5-4C
Univariate Effects of Individual Variables (p<0.01) on Prevalence of HbA1c<7.0% Post Last Infusion among Recipients Aged 18 to 35 Years

Collagenase P (p=<.0001)



Donor gender (p=0.0076)

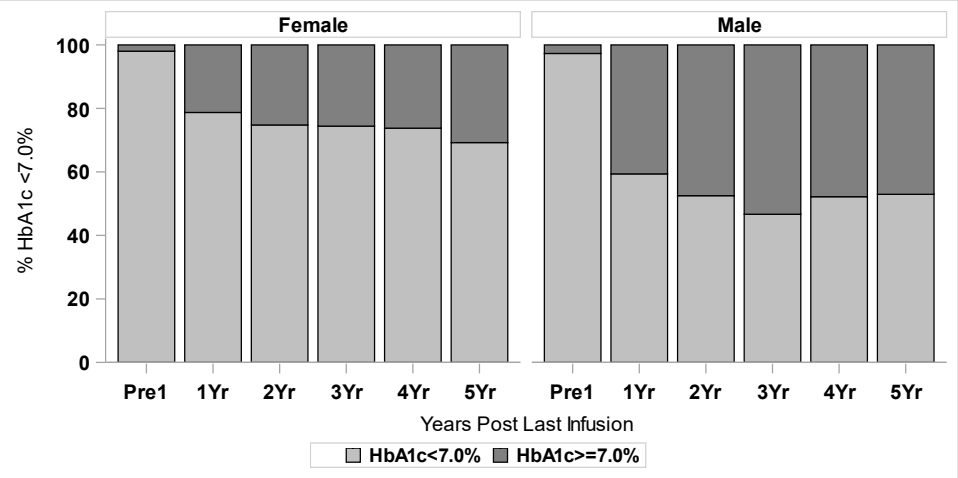
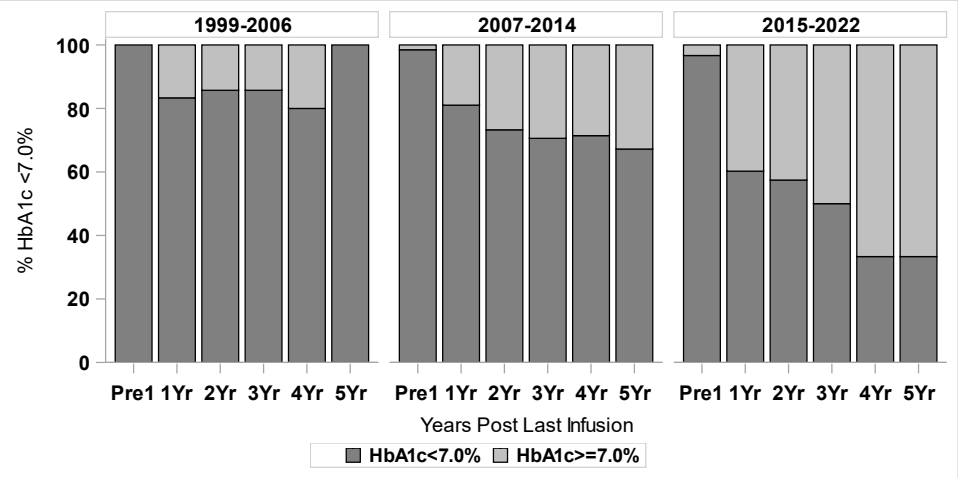


Exhibit 5-4C
Univariate Effects of Individual Variables (p<0.01) on Prevalence of HbA1c<7.0% Post Last Infusion among Recipients Aged 18 to 35 Years

Era (p=0.0034)



Gender (p=0.0076)

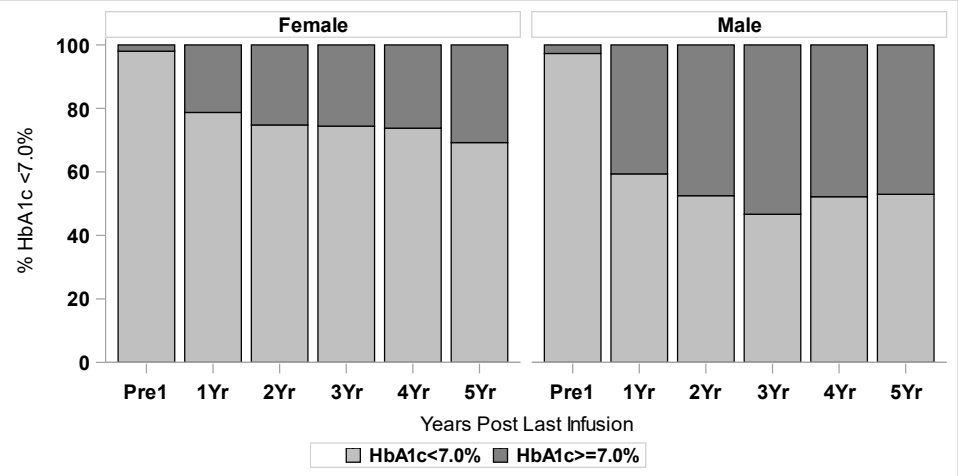
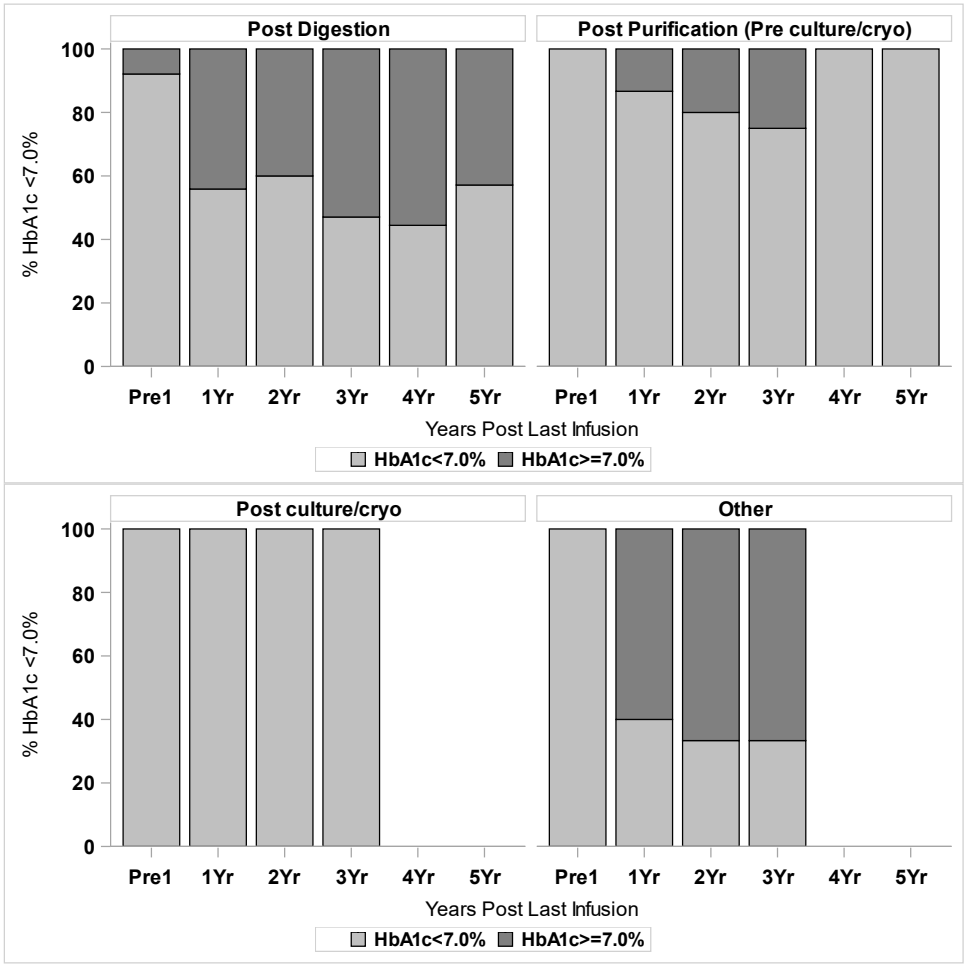


Exhibit 5-4C
Univariate Effects of Individual Variables (p<0.01) on Prevalence of HbA1c<7.0% Post Last Infusion among Recipients Aged 18 to 35 Years

Time of IEQ count (p=0.0002)



Islets IEQs/kg recipient (p=0.0030)

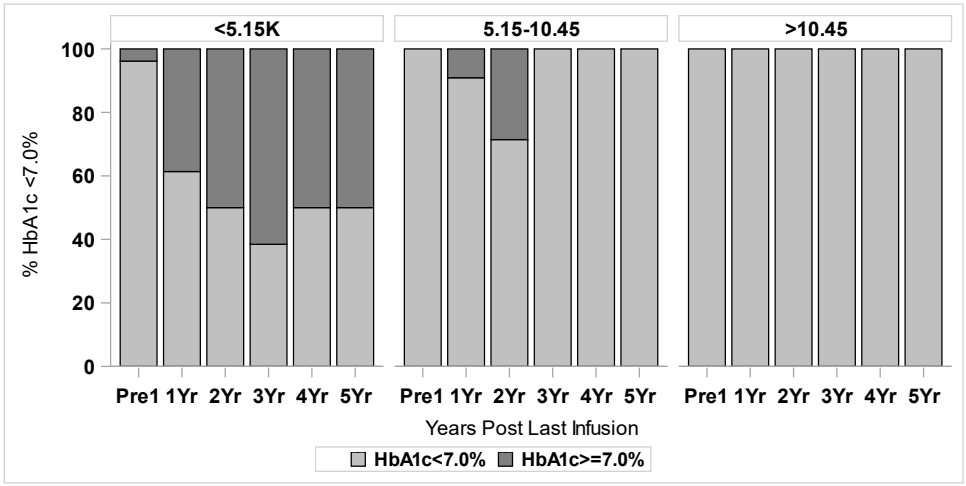
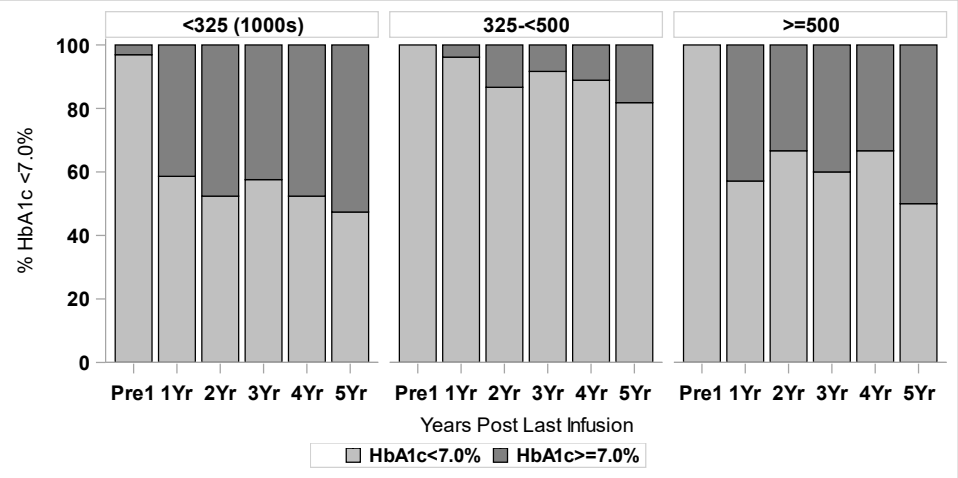


Exhibit 5-4C
Univariate Effects of Individual Variables (p<0.01) on Prevalence of HbA1c<7.0% Post Last Infusion among Recipients Aged 18 to 35 Years

Islets IEQs infused (p=0.0002)



Islet purification (p=<.0001)

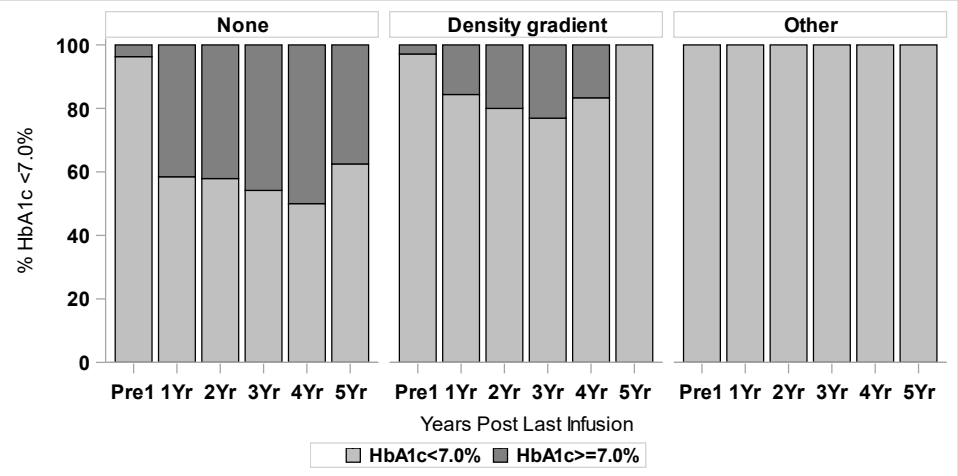
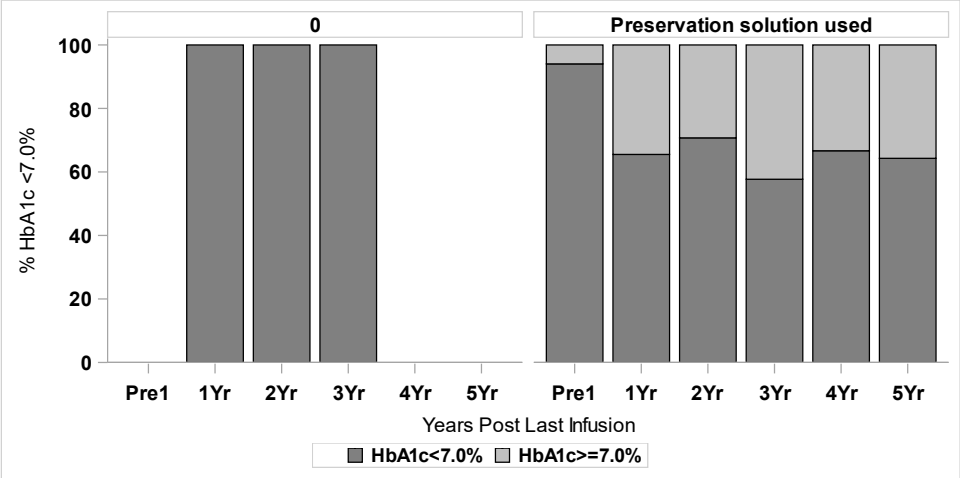


Exhibit 5-4C
Univariate Effects of Individual Variables (p<0.01) on Prevalence of HbA1c<7.0% Post Last Infusion among Recipients Aged 18 to 35 Years

Preservation solution used (0-No 1-Yes) (p=<.0001)



2L preservation (p=<.0001)

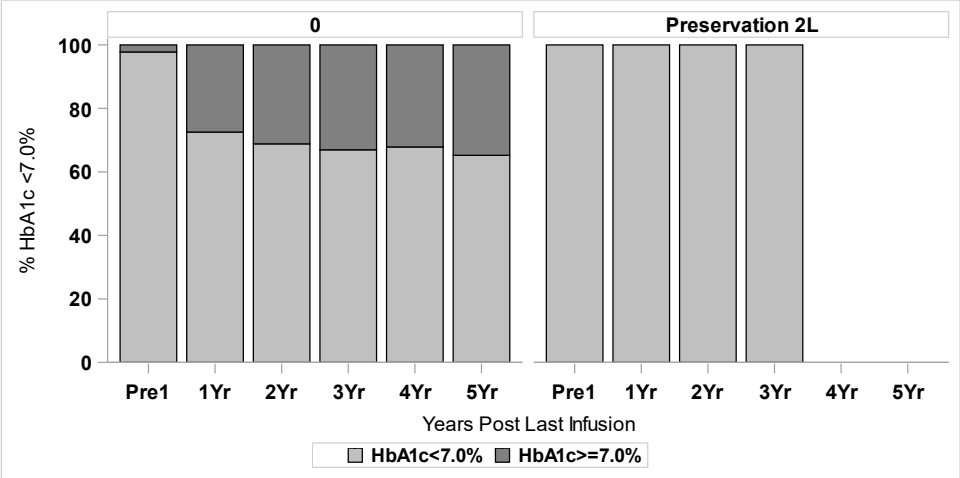
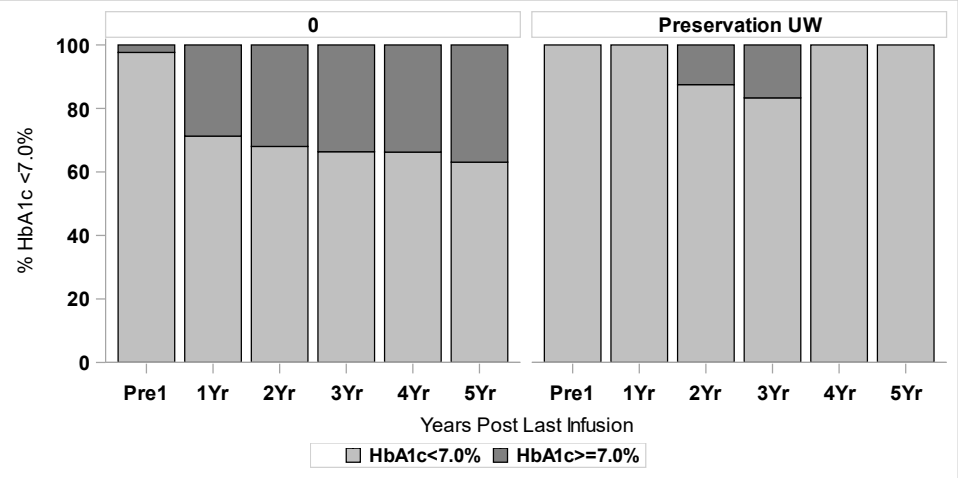


Exhibit 5-4C
Univariate Effects of Individual Variables (p<0.01) on Prevalence of HbA1c<7.0% Post Last Infusion among Recipients Aged 18 to 35 Years

UW preservation (p=<.0001)



Pancreatectomy type (p=<.0001)

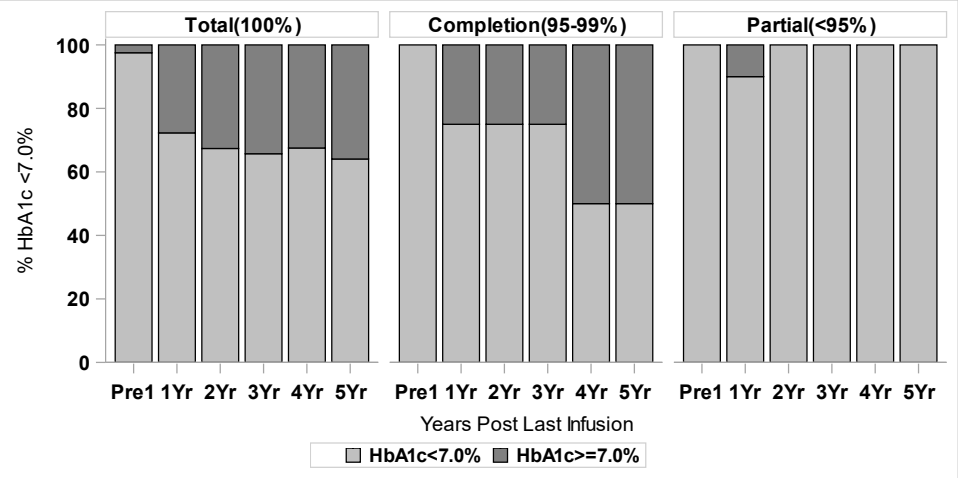
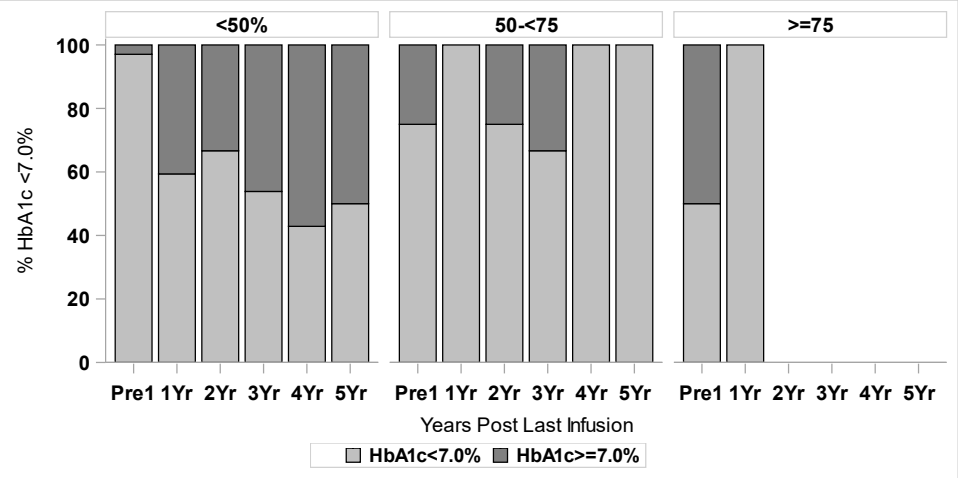


Exhibit 5-4C
Univariate Effects of Individual Variables (p<0.01) on Prevalence of HbA1c<7.0% Post Last Infusion among Recipients Aged 18 to 35 Years

Islets purity (p=0.0046)



Islets IEQs/particle ratio (p=0.0093)

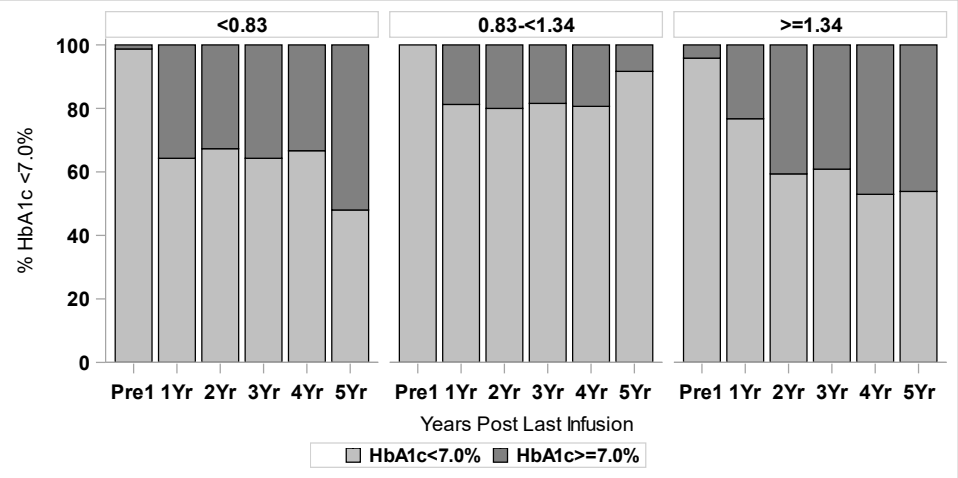
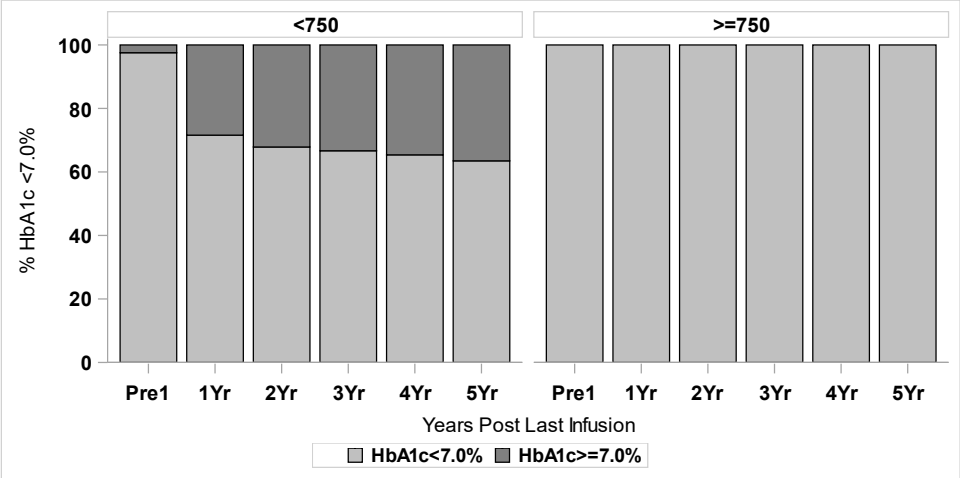


Exhibit 5-4C
Univariate Effects of Individual Variables (p<0.01) on Prevalence of HbA1c<7.0% Post Last Infusion among Recipients Aged 18 to 35 Years

Islets IEQ count (p=<.0001)



Indication: Cancer (0-No 1-Yes) (p=<.0001)

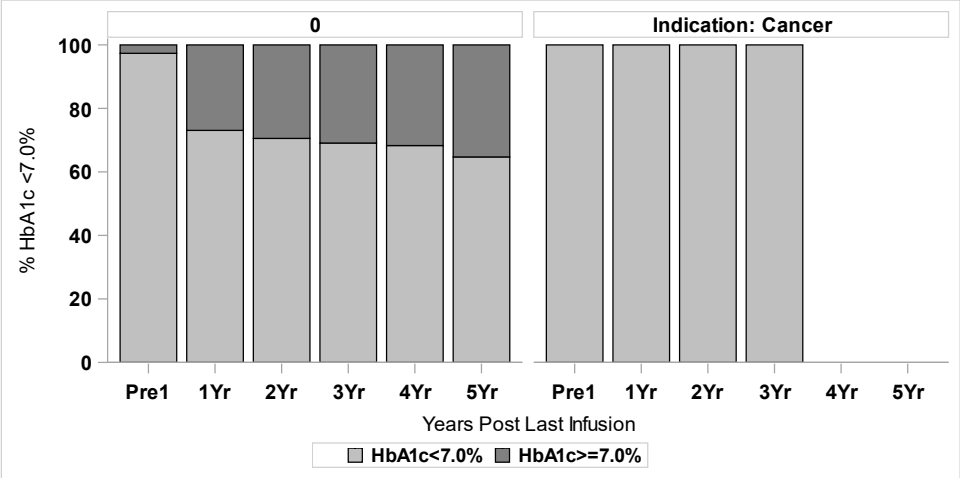
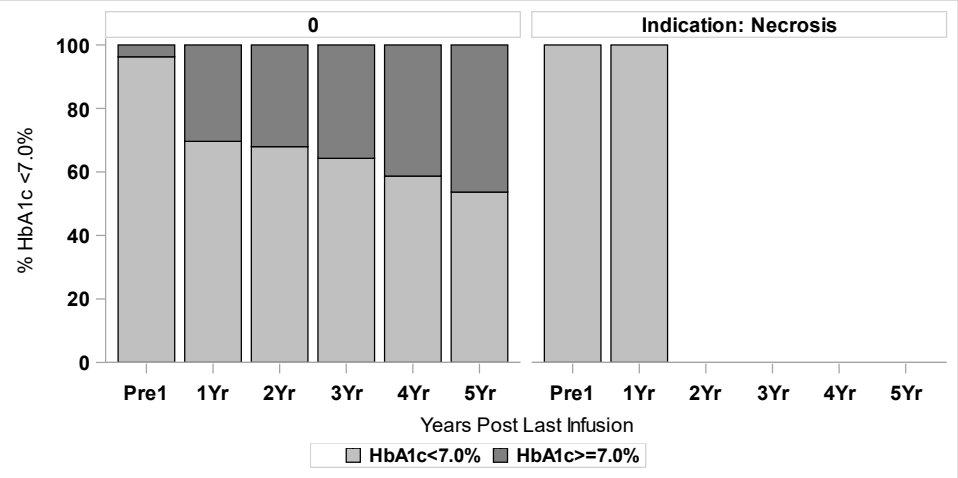


Exhibit 5-4C
Univariate Effects of Individual Variables (p<0.01) on Prevalence of HbA1c<7.0% Post Last Infusion among Recipients Aged 18 to 35 Years

Indication: Necrosis (0-No 1-Yes) (p=<.0001)



Indication: Other (0-No 1-Yes) (p=<.0001)

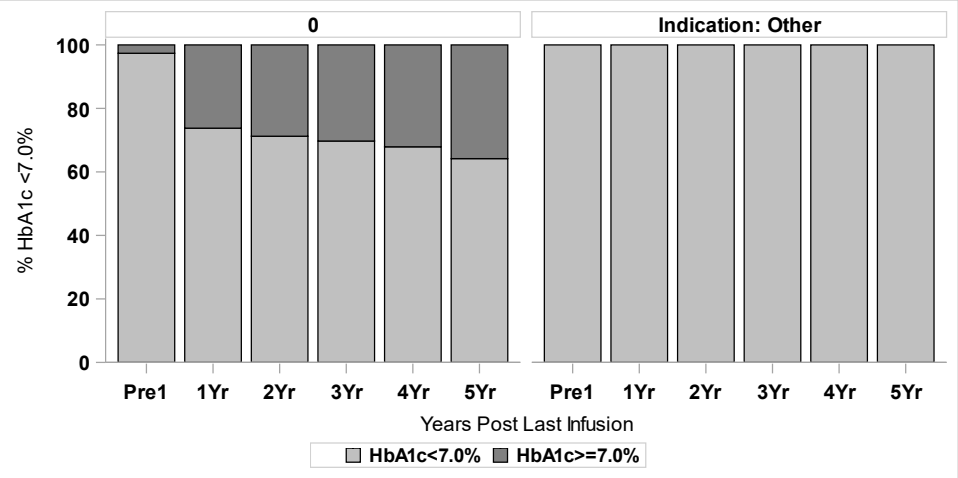
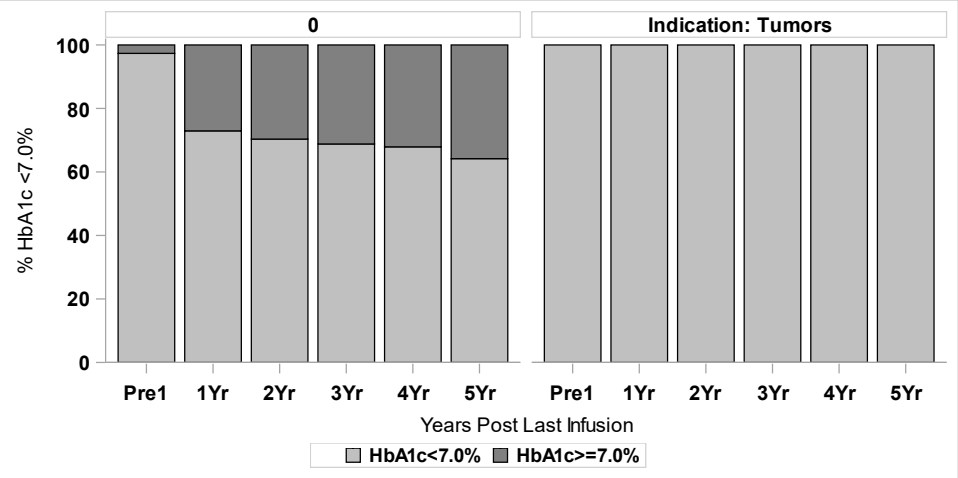


Exhibit 5-4C
Univariate Effects of Individual Variables (p<0.01) on Prevalence of HbA1c<7.0% Post Last Infusion among Recipients Aged 18 to 35 Years

Indication: Tumors (0-No 1-Yes) (p=<.0001)



Type of transplant (p=<.0001)

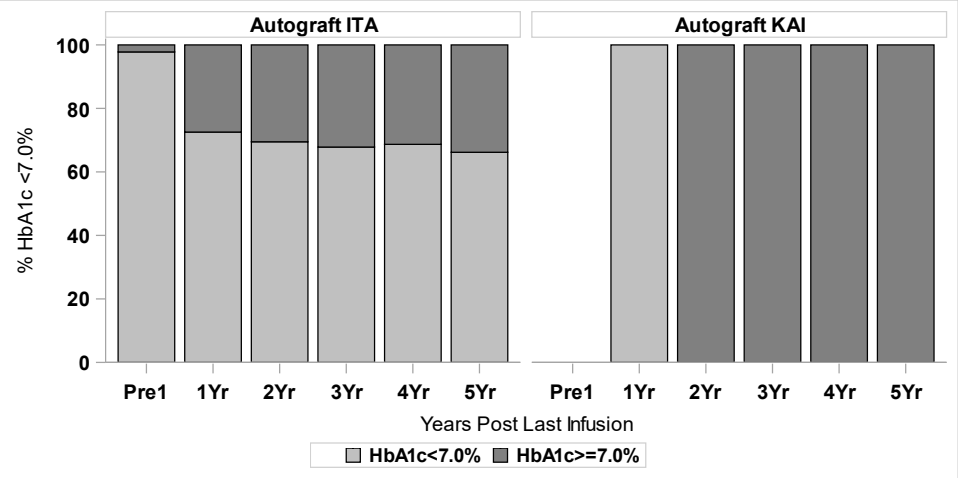


Exhibit 5-5A
Prevalence of Absence of Severe Hypoglycemic Events Post Last Infusion by Age Group (p=<.0001)

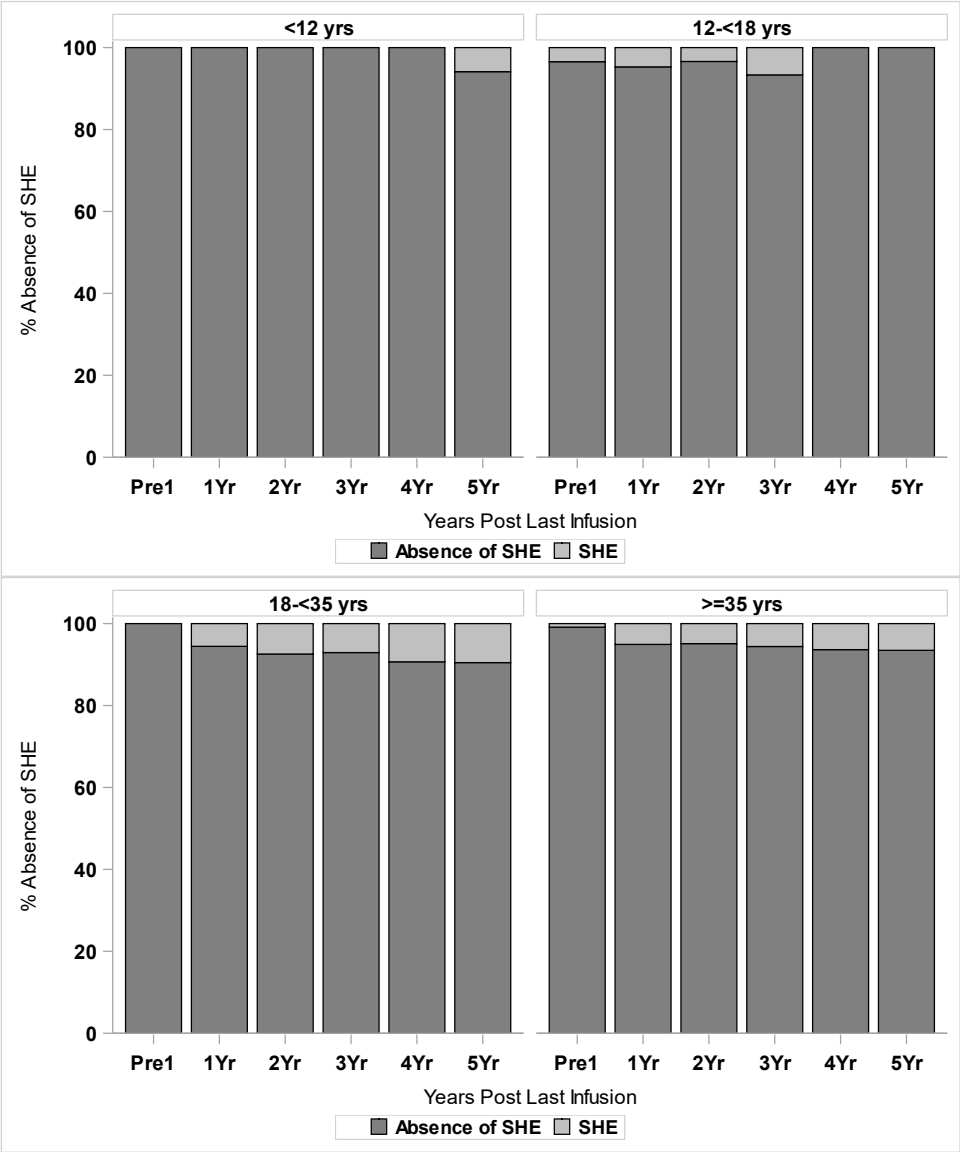
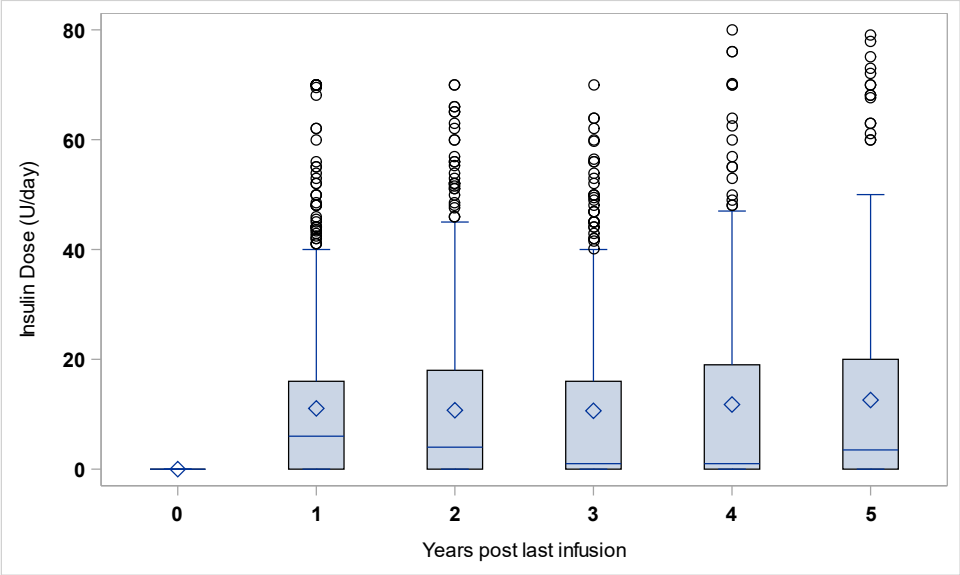


Exhibit 5-6
Insulin Dose (U/day) Post Last Infusion

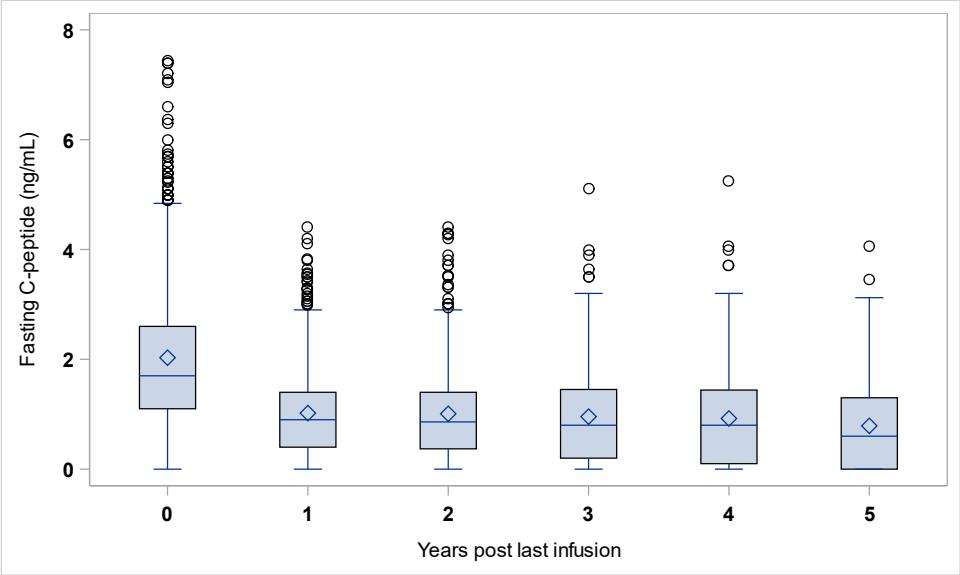
Overall



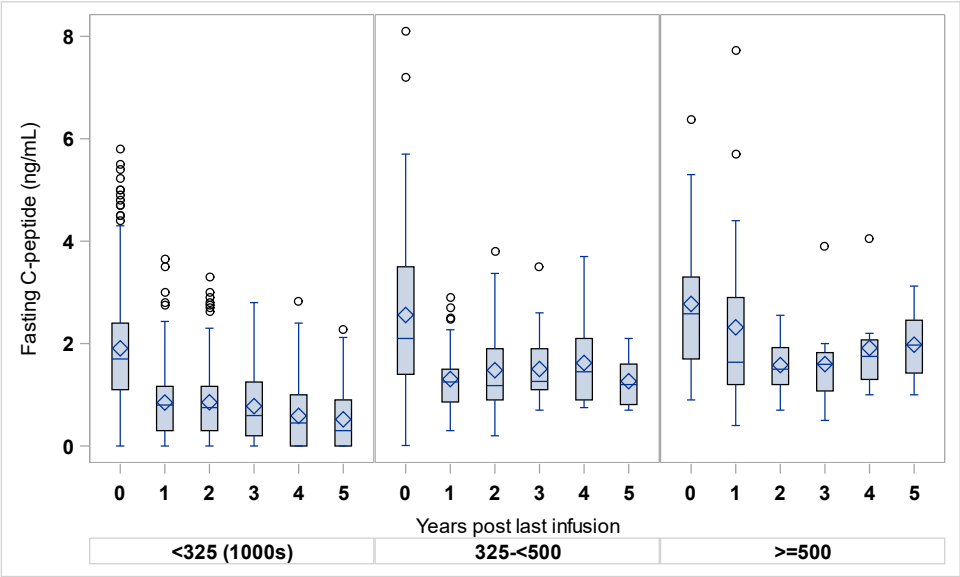
Extreme outliers (outside of 3*IQR less than the lower quartile or 3*IQR more than the upper quartile) are excluded from box plots.
An exhibit having only an 'Overall' plot indicates that no significant factors (p<0.01) were found.

Exhibit 5-7
Fasting C-peptide (ng/mL) Post Last Infusion

Overall



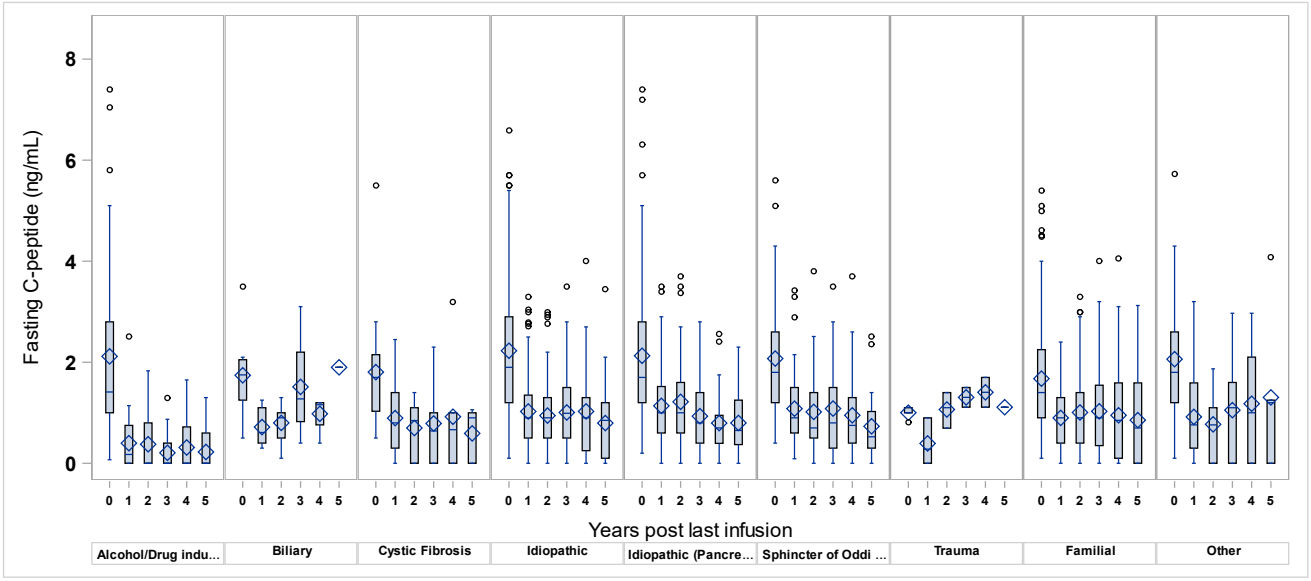
Total IEQs (all infusions) (p=<.0001)



Extreme outliers (outside of 3*IQR less than the lower quartile or 3*IQR more than the upper quartile) are excluded from box plots.
An exhibit having only an 'Overall' plot indicates that no significant factors (p<0.01) were found.

Exhibit 5-7
Fasting C-peptide (ng/mL) Post Last Infusion

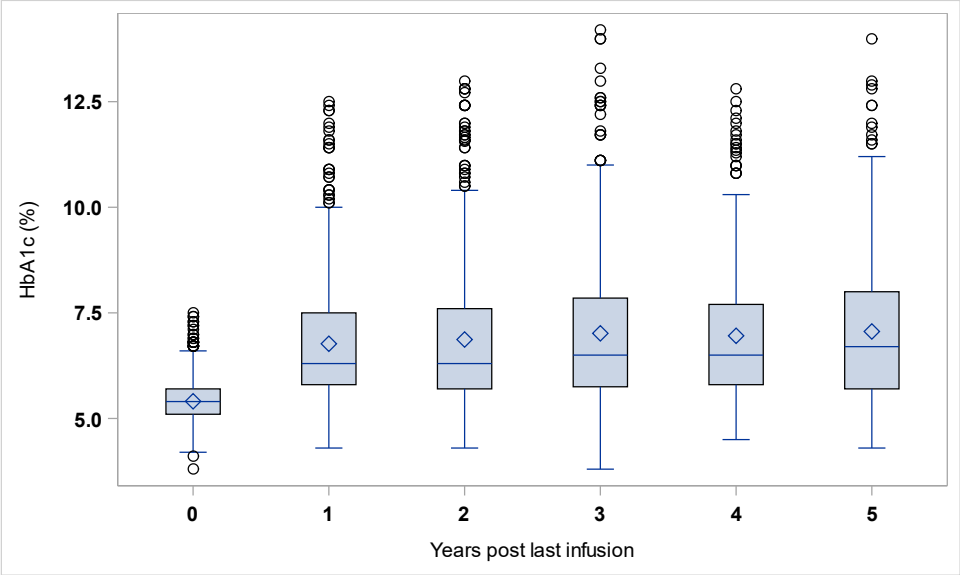
Pancreatitis Etiology (p=0.0047)



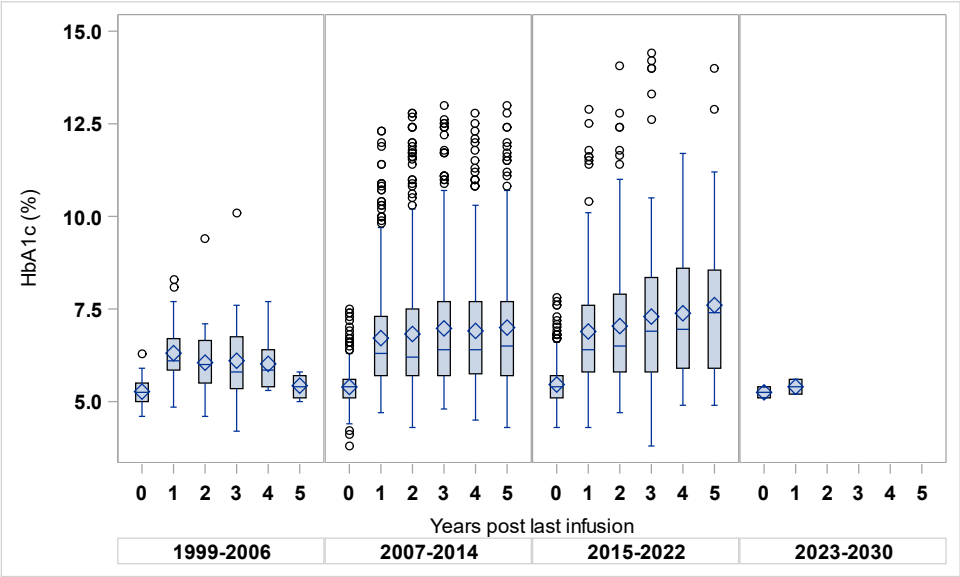
Extreme outliers (outside of 3*IQR less than the lower quartile or 3*IQR more than the upper quartile) are excluded from box plots.
An exhibit having only an 'Overall' plot indicates that no significant factors (p<0.01) were found.

Exhibit 5-8
HbA1c (%) Post Last Infusion

Overall



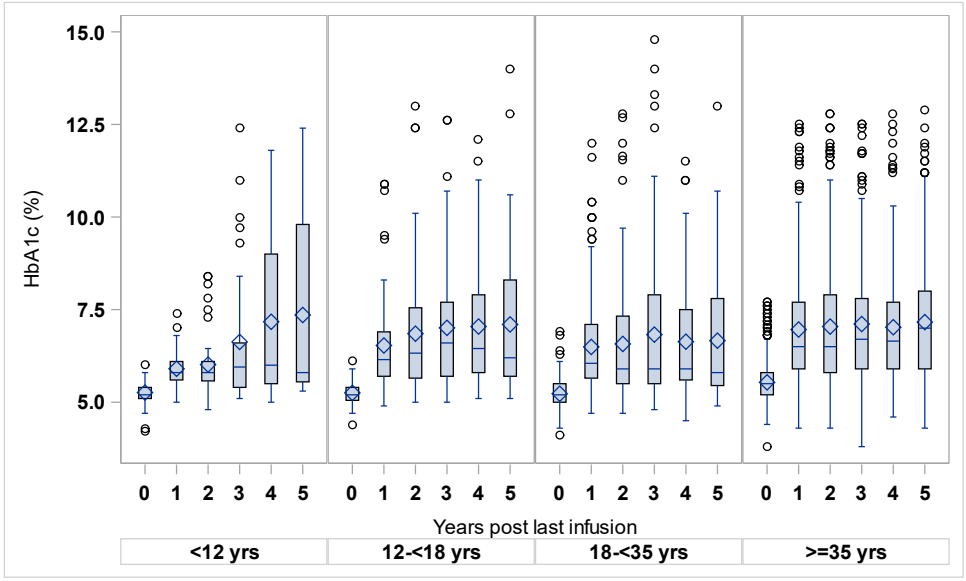
Era (p=0.0071)



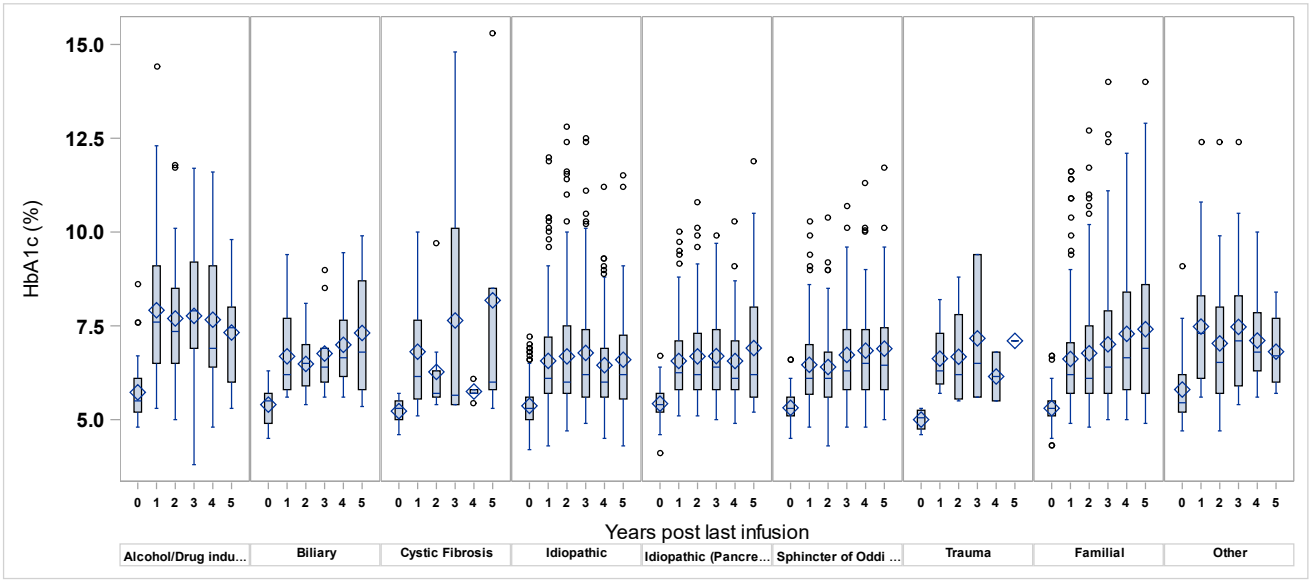
Extreme outliers (outside of 3*IQR less than the lower quartile or 3*IQR more than the upper quartile) are excluded from box plots.
An exhibit having only an 'Overall' plot indicates that no significant factors (p<0.01) were found.

Exhibit 5-8
HbA1c (%) Post Last Infusion

Age (p=<.0001)



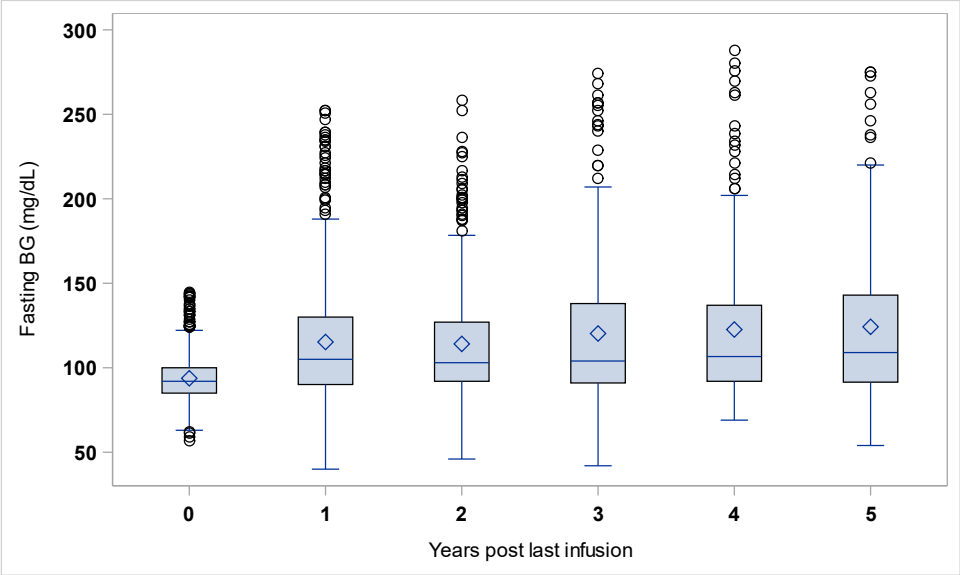
Pancreatitis Etiology (p=<.0001)



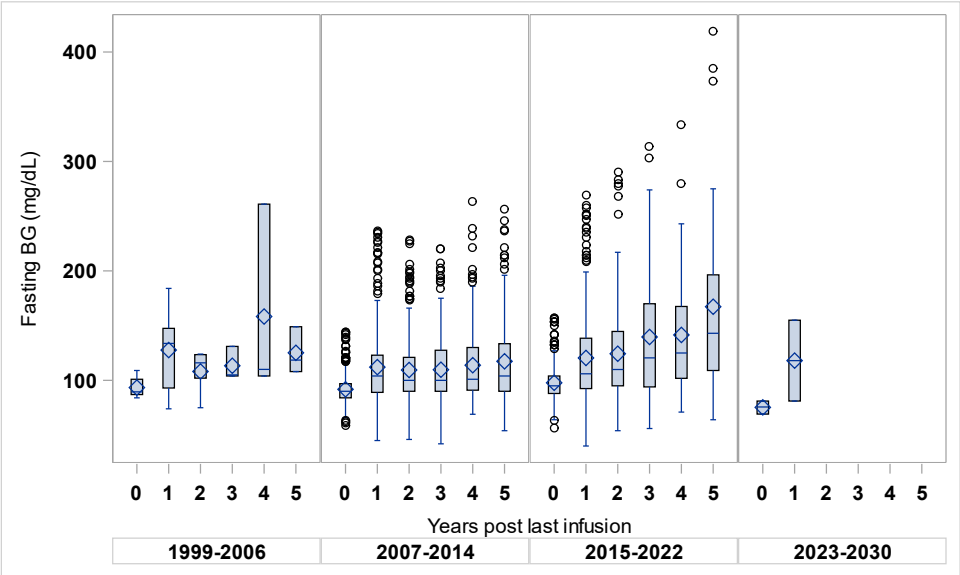
Extreme outliers (outside of 3*IQR less than the lower quartile or 3*IQR more than the upper quartile) are excluded from box plots.
An exhibit having only an 'Overall' plot indicates that no significant factors (p<0.01) were found.

Exhibit 5-9
Fasting Blood Glucose (mg/dL) Post Last Infusion

Overall



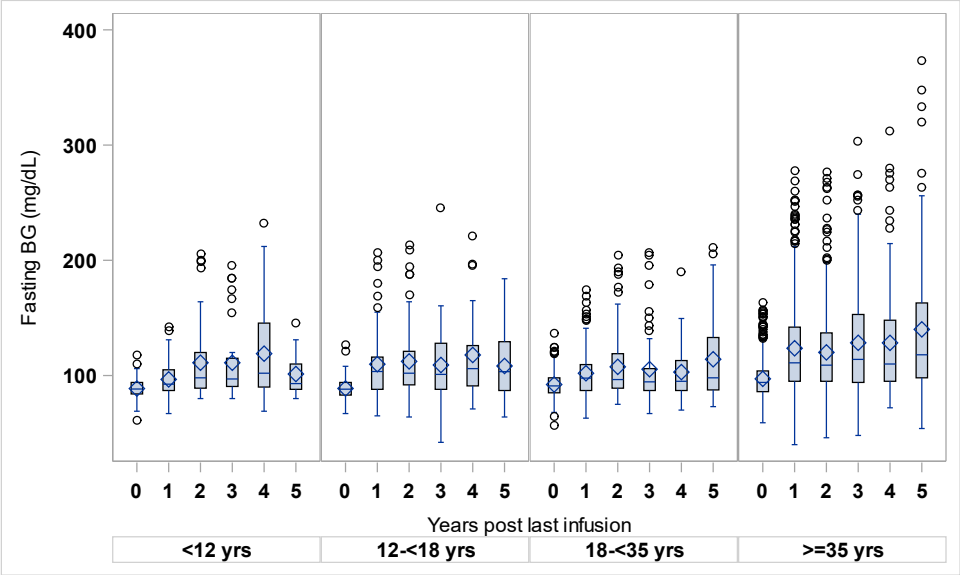
Era (p=0.0014)



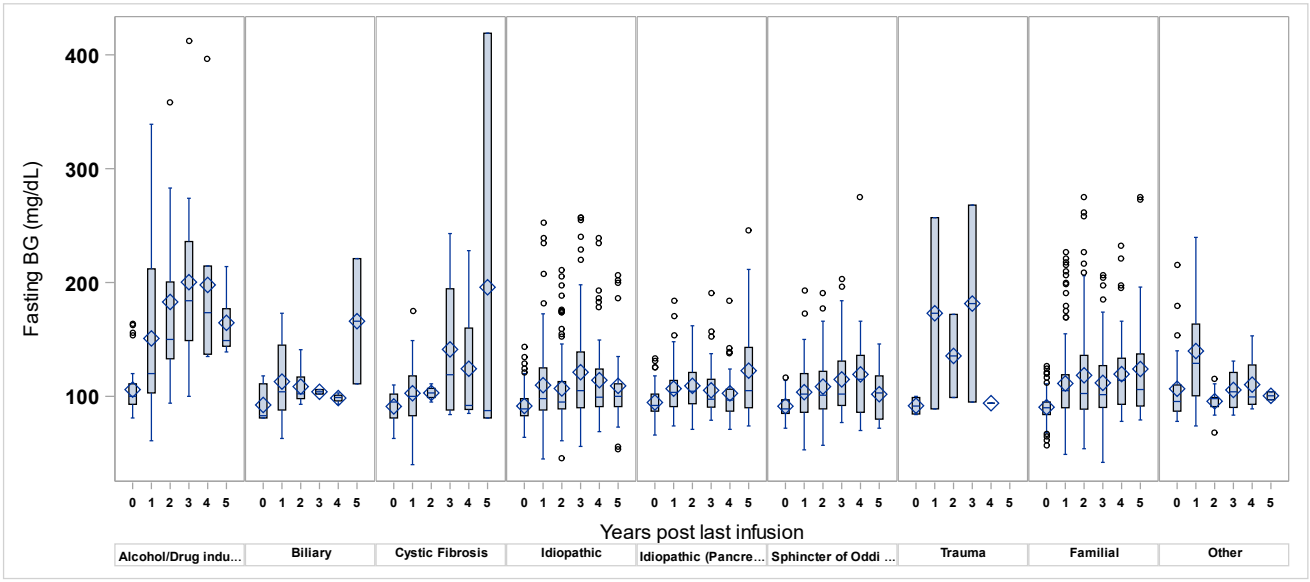
Extreme outliers (outside of 3*IQR less than the lower quartile or 3*IQR more than the upper quartile) are excluded from box plots.
An exhibit having only an 'Overall' plot indicates that no significant factors (p<0.01) were found.

Exhibit 5-9
Fasting Blood Glucose (mg/dL) Post Last Infusion

Age (p=<.0001)



Pancreatitis Etiology (p=<.0001)



Extreme outliers (outside of 3*IQR less than the lower quartile or 3*IQR more than the upper quartile) are excluded from box plots.
An exhibit having only an 'Overall' plot indicates that no significant factors (p<0.01) were found.

Appendix A: Autologous Islet Transplant Center Contributors

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