2nd Autograft Report

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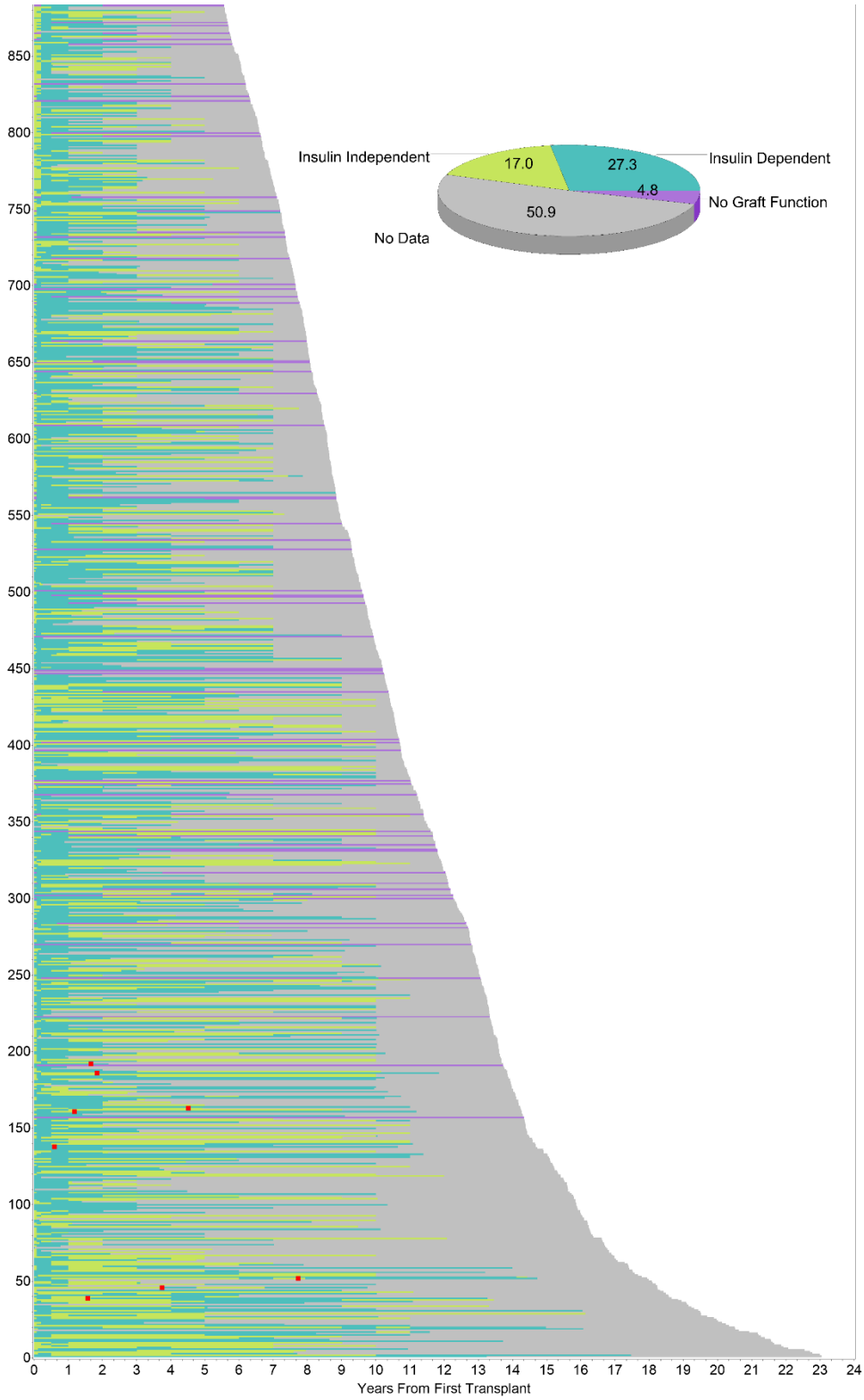


Collaborative Islet Transplant Registry 2022

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

Chapter 1

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 2020, with follow-up data through February 2022.

Of 26 North American sites performing Auto-ITx during this period, 15 reported data to CITR, along with 5 European and Australian islet transplant centers. These sites registered 1233 auto-islet transplant recipients. Of these, 1123 recipients were in North America, 98 in Europe, and 12 in Australia. One-hundred eight-five (185) were aged less than 18, and 1,057 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, after the initial rise in annual transplants performed from 1999 through 2007, with subsequent leveling off thereafter. The light gray bars show the sites already members of CITR or identified via an online survey conducted by CITR, while the dark gray bars show the transplants registered in CITR. A few additional cases of Auto-Itx may be performed at sites not affiliated with an islet processing center, but those would be few.

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

Chapter 2

Exhibit 1 – 1A
Auto-Islet Recipients

CITR-Consented AUTO Recipients	North America	Europe	Australia	All
N	1123	98	12	1233

Exhibit 1 – 1B
Auto-Islet Infusions

AUTO Infusions	Pediatric		Adult		All
	North America	Europe/ Australia/Asia	North America	Europe/ Australia/Asia	
N	179	6	952	105	1242

Exhibit 1 – 2
Cumulative Auto-Islet Recipient Enrollment (by date of transplant)

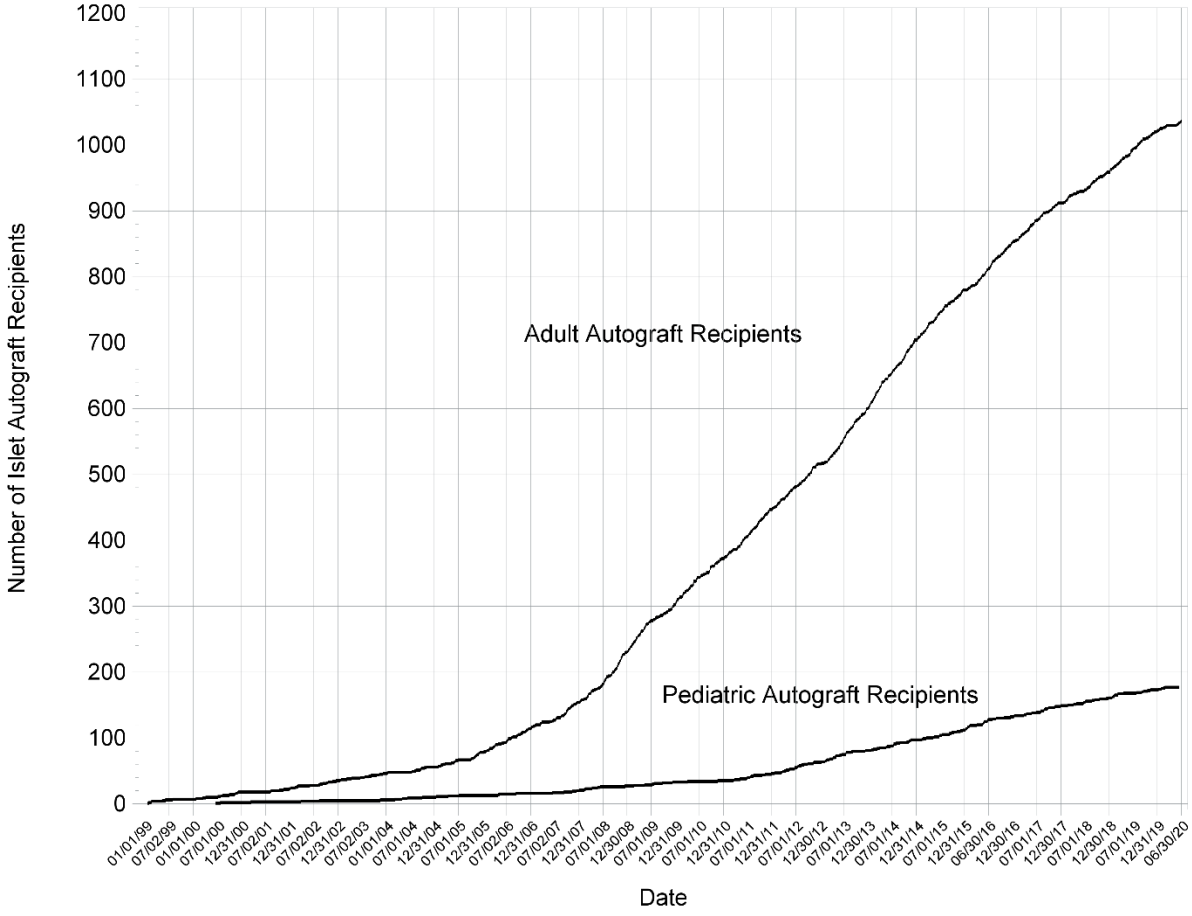


Exhibit 1 – 3

Clinical sites performing islet autograft transplantation, by year – North America

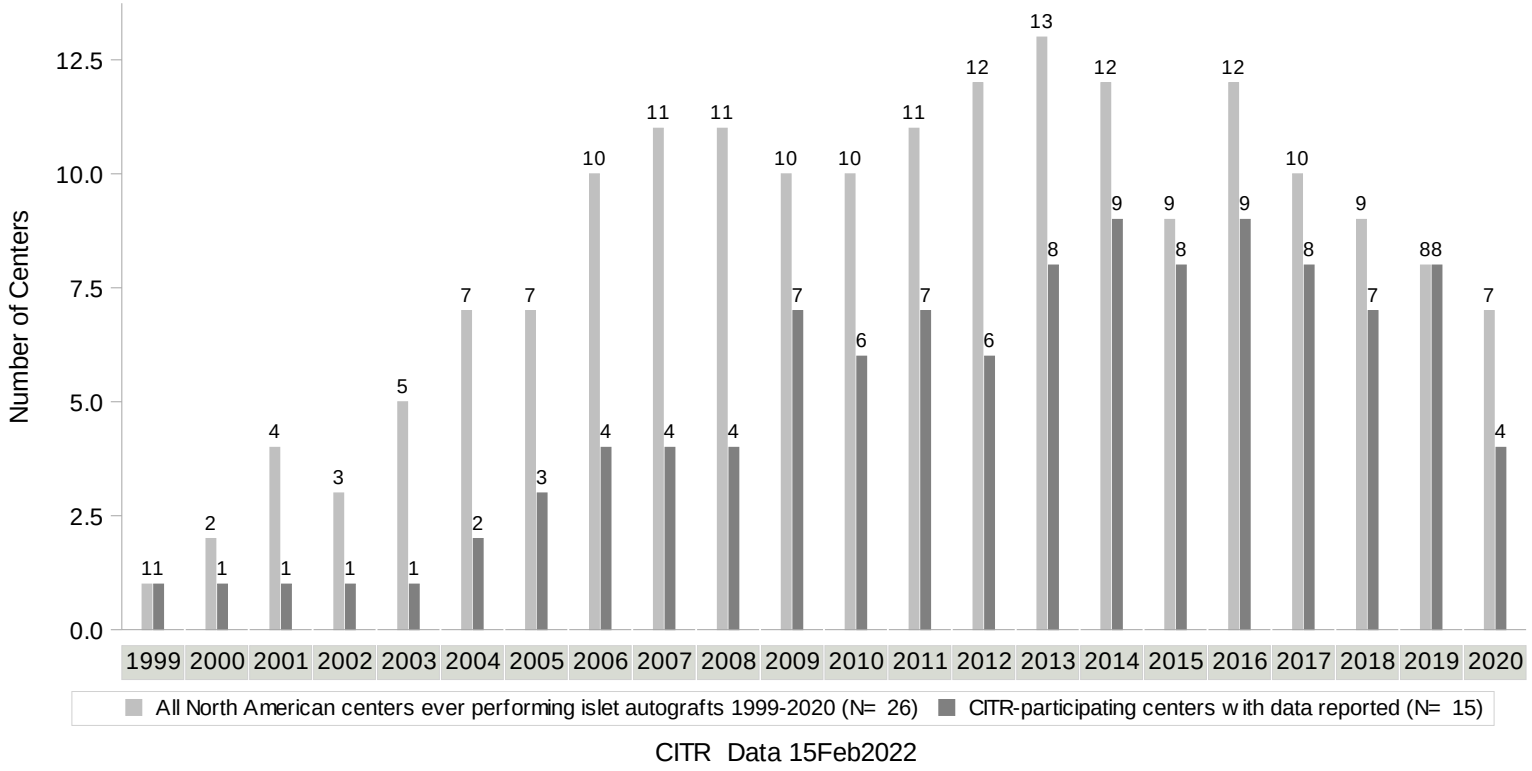
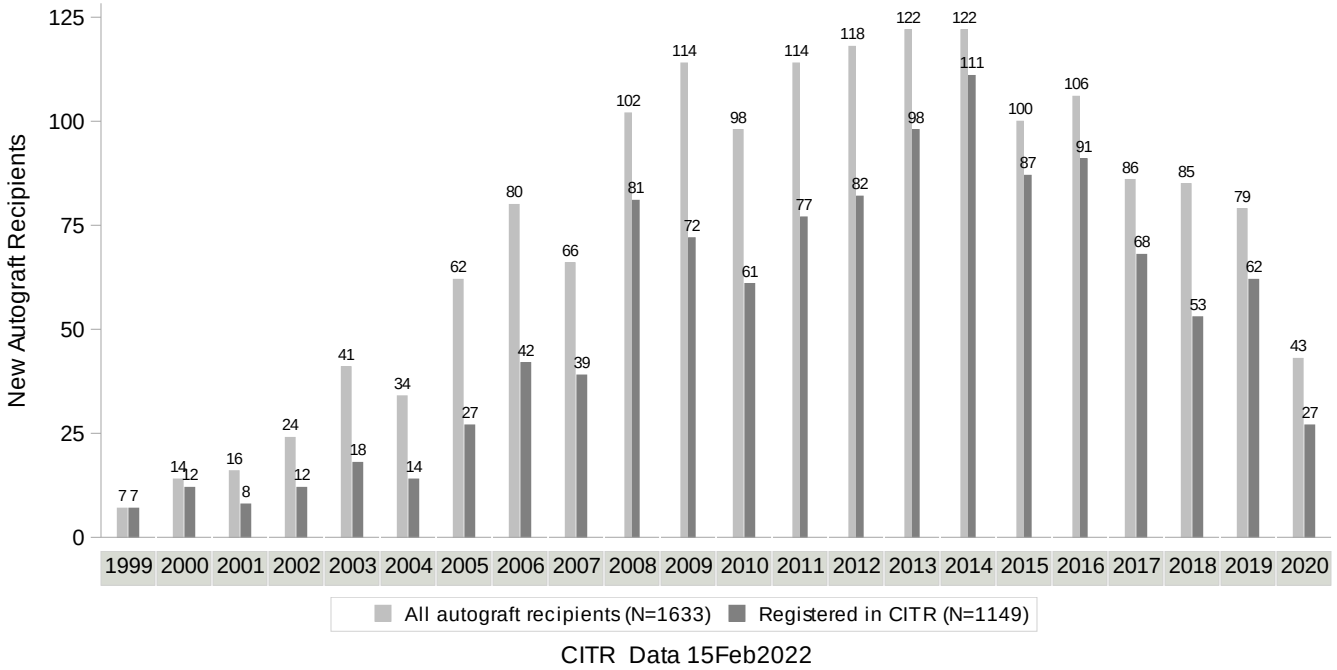


Exhibit 1 – 4A

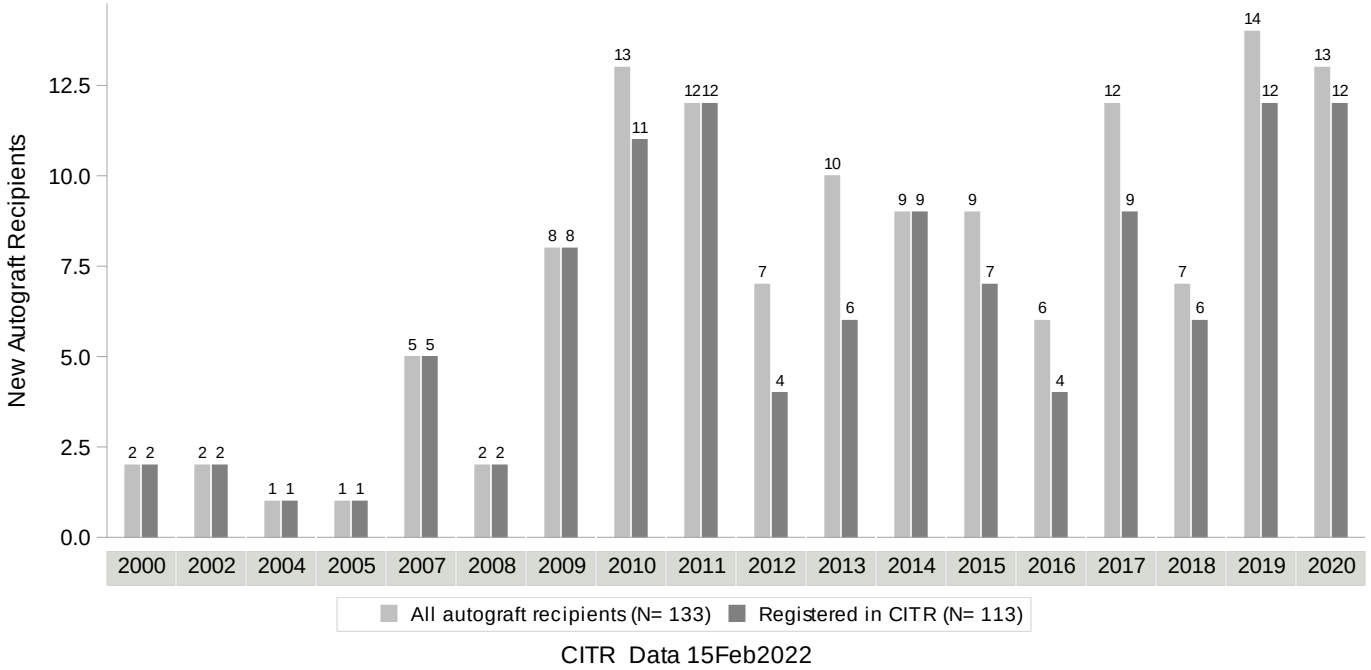
New islet autograft transplant enrollment, by year of first transplant – North America



CITR Data 15Feb2022

Exhibit 1 – 4B

New islet autograft transplant enrollment, by year of first transplant – Europe and Australia



CITR Data 15Feb2022

Exhibit 1 – 5
First and second autograft transplants, by year of transplant

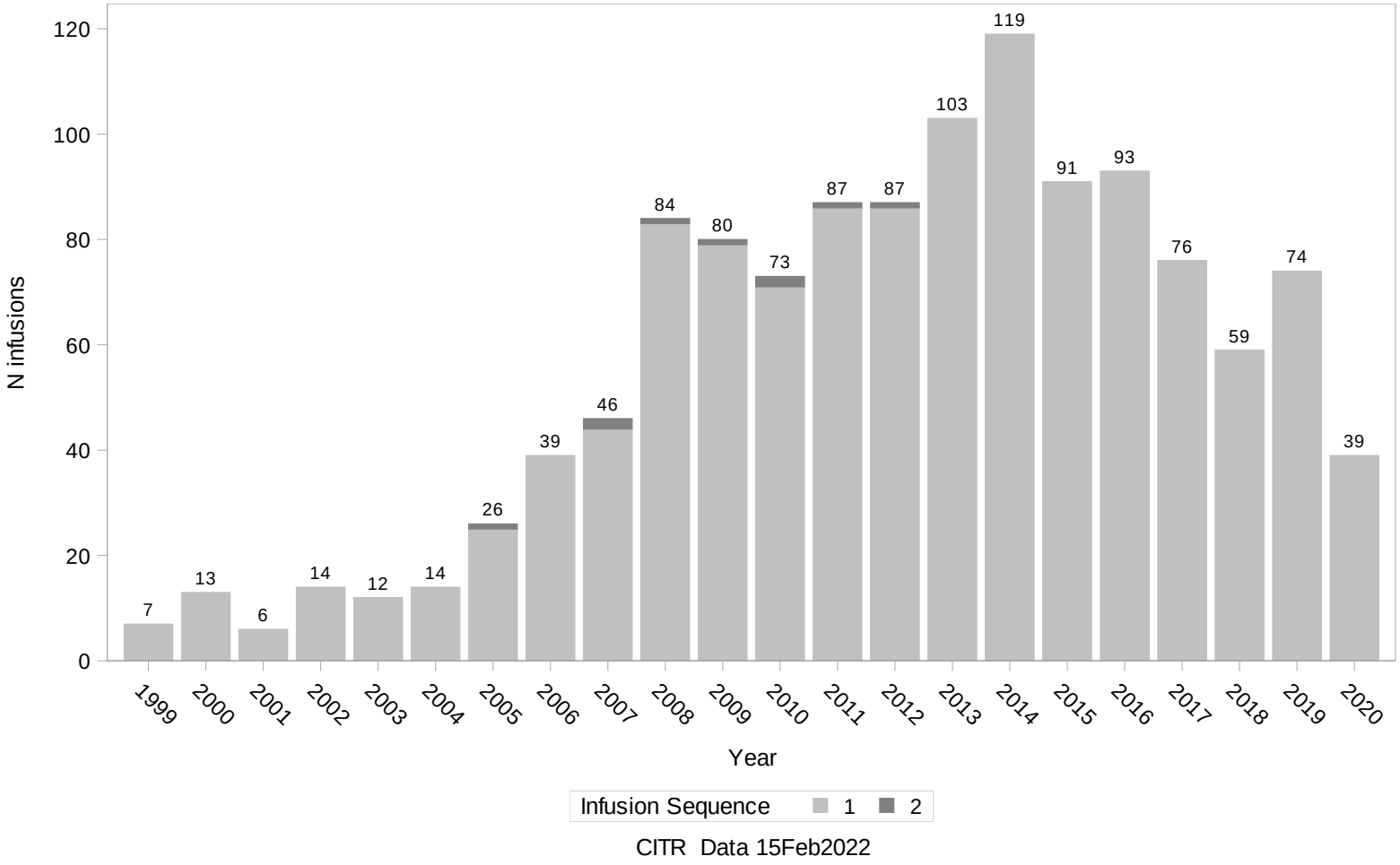
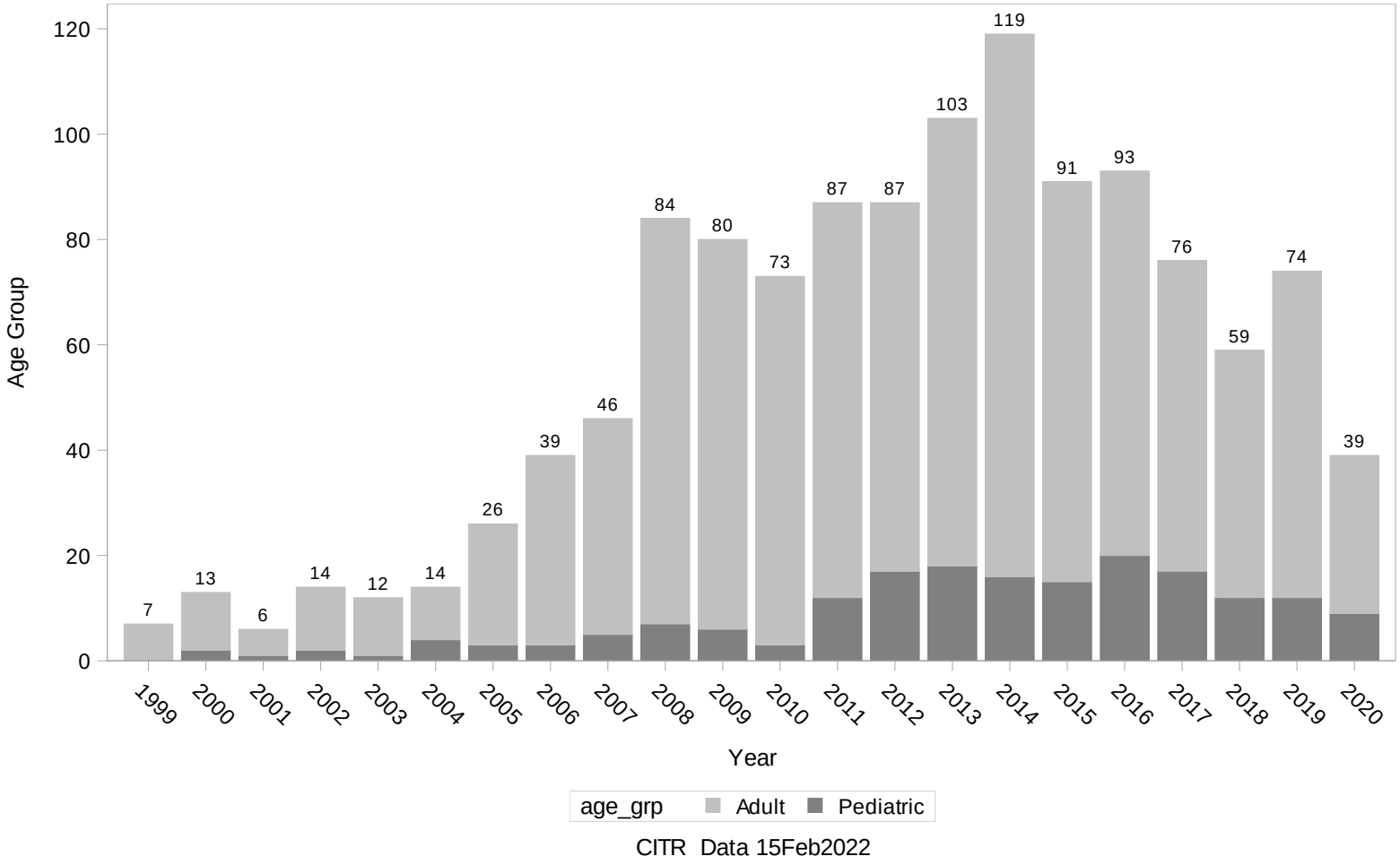


Exhibit 1 – 6

Adult and pediatric autograft transplants, by year of transplant



Chapter 3

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 (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 the age groups, ranged within normal levels. As a mixture of indications for pancreatectomy and auto-islet transplantation, the CITR Auto-Itx group shows varying levels of insulin requirement prior to infusion: none of the children <12 years old (yo) required any insulin, 3% of the 12-18 yo's required insulin, 3% of the the 18-<35 yo's required insulin, and 6.5% ≥35 yo's required insulin (Exhibit 2-2B).

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

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

Pancreatitis as the reason for the pancreatectomy declined from 95% 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.

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

Exhibit 2 – 1

Recipient Demographics

		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Gender	Female	42	63.6	70	60.3	215	68.5	508	68.9	
	Male	24	36.4	46	39.7	99	31.5	229	31.1	

Data Completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Gender	Available	66	100.0	116	100.0	314	100.0	737	100.0	

		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	p
Gender	Female	25	62.5	63	70.0	207	74.7	257	65.2	213	66.8	70	61.9	
	Male	15	37.5	27	30.0	70	25.3	137	34.8	106	33.2	43	38.1	

Data completeness		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
Gender	Available	40	100.0	90	100.0	277	100.0	394	100.0	319	100.0	113	100.0	

		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Race	American Indian/Alaska Native	0	0.0	0	0.0	2	1.5	2	0.5	
	Asian	2	22.2	0	0.0	0	0.0	4	1.0	
	Black or African American	0	0.0	0	0.0	5	3.7	21	5.1	***
	Multiple	1	11.1	1	3.0	0	0.0	0	0.0	
	Other	1	11.1	5	15.2	2	1.5	5	1.2	
	White	5	55.6	27	81.8	126	93.3	381	92.3	

Data Completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Race	Available	9	13.6	33	28.4	135	43.0	413	56.0	
	Missing	57	86.4	83	71.6	179	57.0	324	44.0	

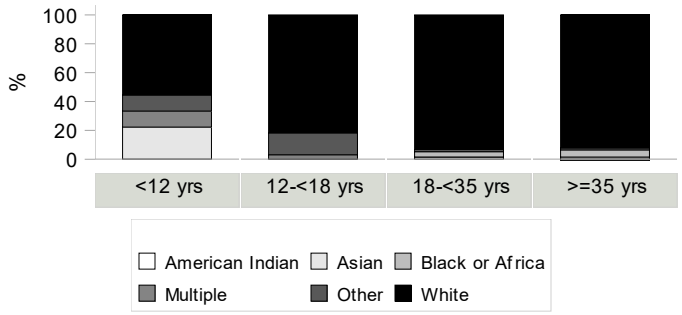
*=p<.05; **=p<.01; ***=p<.001

Exhibit 2 – 1 (continued)
Recipient Demographics

		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	p
Race	American Indian/Alaska Native	0	0.0	0	0.0	0	0.0	3	1.6	0	0.0	1	1.8	
	Asian	1	2.7	0	0.0	1	1.0	0	0.0	4	2.5	0	0.0	
	Black or African American	0	0.0	2	4.2	9	8.9	9	4.7	6	3.8	0	0.0	
	Multiple	0	0.0	0	0.0	0	0.0	1	0.5	1	0.6	0	0.0	
	Other	0	0.0	0	0.0	1	1.0	2	1.1	6	3.8	4	7.1	
	White	36	97.3	46	95.8	90	89.1	175	92.1	141	89.2	51	91.1	

Data completeness		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
Race	Available	37	92.5	48	53.3	101	36.5	190	48.2	158	49.5	56	49.6	
	Missing	3	7.5	42	46.7	176	63.5	204	51.8	161	50.5	57	50.4	

Race



CITR Data 15Feb2022

		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Ethnicity	Hispanic or Latino	0	0.0	4	12.5	5	3.8	9	2.2	*
	Not Hispanic or Latino	9	100.0	28	87.5	127	96.2	397	97.8	

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

Exhibit 2 – 1 (continued)
Recipient Demographics

Data Completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Ethnicity	Available	9	13.6	32	27.6	132	42.0	406	55.1	
	Missing	57	86.4	84	72.4	182	58.0	331	44.9	

		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	p
Ethnicity	Hispanic or Latino	0	0.0	0	0.0	1	1.0	7	3.6	8	4.9	2	3.7	
	Not Hispanic or Latino	26	100.0	44	100.0	99	99.0	185	96.4	155	95.1	52	96.3	

Data completeness		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
Ethnicity	Available	26	65.0	44	48.9	100	36.1	192	48.7	163	51.1	54	47.8	
	Missing	14	35.0	46	51.1	177	63.9	202	51.3	156	48.9	59	52.2	

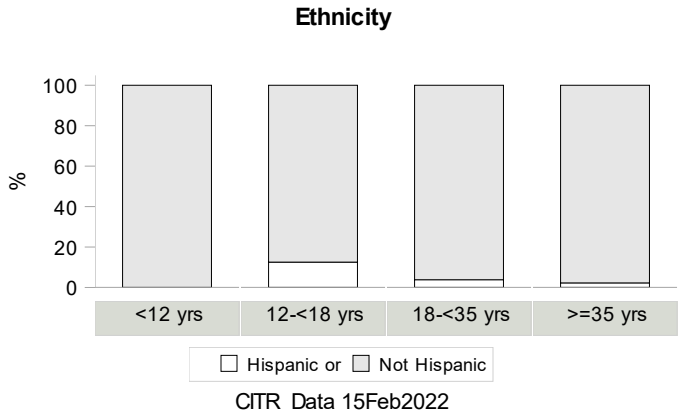


Exhibit 2 – 2A

Recipient Characteristics at First Infusion

	Age Group												
	<12 yrs			12-<18 yrs			18-<35 yrs			>=35 yrs			
	N	Mean	SE	N	Mean	SE	N	Mean	SE	N	Mean	SE	p
Age at transplant	66	8.3	0.3	116	15.3	0.2	314	27.2	0.3	737	48.3	0.3	***
Weight (kg)	31	29.9	2.5	55	62.3	2.3	155	73.5	1.5	426	72.8	0.8	***
Body Mass Index (kg/m^2)	7	17.4	0.8	22	24.3	1.2	104	25.9	0.6	318	25.6	0.3	**
Daily insulin requirement prior to infusion (units)	60	0.0	0.0	107	0.5	0.3	272	1.4	0.6	603	1.7	0.3	*
Avg daily insulin / kg recipient body weight	26	0.0	0.0	48	0.0	0.0	129	0.0	0.0	337	0.0	0.0	
Fasting plasma glucose (mg/dL)	49	88.6	1.3	84	88.8	1.1	201	94.4	1.4	443	101.8	1.5	***
Basal C-Peptide (ng/mL)	48	1.4	0.2	81	2.0	0.1	222	2.1	0.1	517	2.2	0.1	**
HbA1c (%)	56	5.3	0.1	87	5.3	0.1	228	5.3	0.1	535	5.7	0.0	***

	Era																		
	1999-2002			2003-2006			2007-2010			2011-2014			2015-2018			2019-2022			
	N	Mean	SE	N	Mean	SE	N	Mean	SE	N	Mean	SE	N	Mean	SE	N	Mean	SE	p
Age at transplant	40	38.5	2.0	90	36.9	1.4	277	40.2	0.8	394	37.8	0.8	319	35.8	0.9	113	36.7	1.6	*
Weight (kg)	4	61.9	8.7	11	67.4	3.6	83	66.9	1.6	190	71.8	1.2	280	69.7	1.3	99	71.4	2.1	
Body Mass Index (kg/m^2)	4	21.6	1.9	9	25.1	1.8	72	24.1	0.7	181	25.3	0.4	143	26.4	0.5	42	25.7	0.9	
Daily insulin requirement prior to infusion (units)	24	1.8	1.8	78	0.1	0.1	223	1.7	0.6	363	1.0	0.4	261	2.4	0.7	93	0.6	0.3	
Avg daily insulin / kg recipient body weight	4	0.0	0.0	3	0.0	0.0	45	0.0	0.0	166	0.0	0.0	232	0.0	0.0	90	0.0	0.0	
Fasting plasma glucose (mg/dL)	0	-	-	15	93.3	1.9	111	93.6	1.9	331	96.1	1.6	234	100.2	1.6	86	102.7	3.0	*
Basal C-Peptide (ng/mL)	4	1.4	0.3	17	2.6	0.4	176	2.2	0.1	363	1.9	0.1	216	2.2	0.1	92	2.3	0.2	
HbA1c (%)	2	4.7	0.4	27	5.3	0.1	172	5.5	0.0	361	5.5	0.0	254	5.7	0.1	90	5.6	0.1	*

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

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

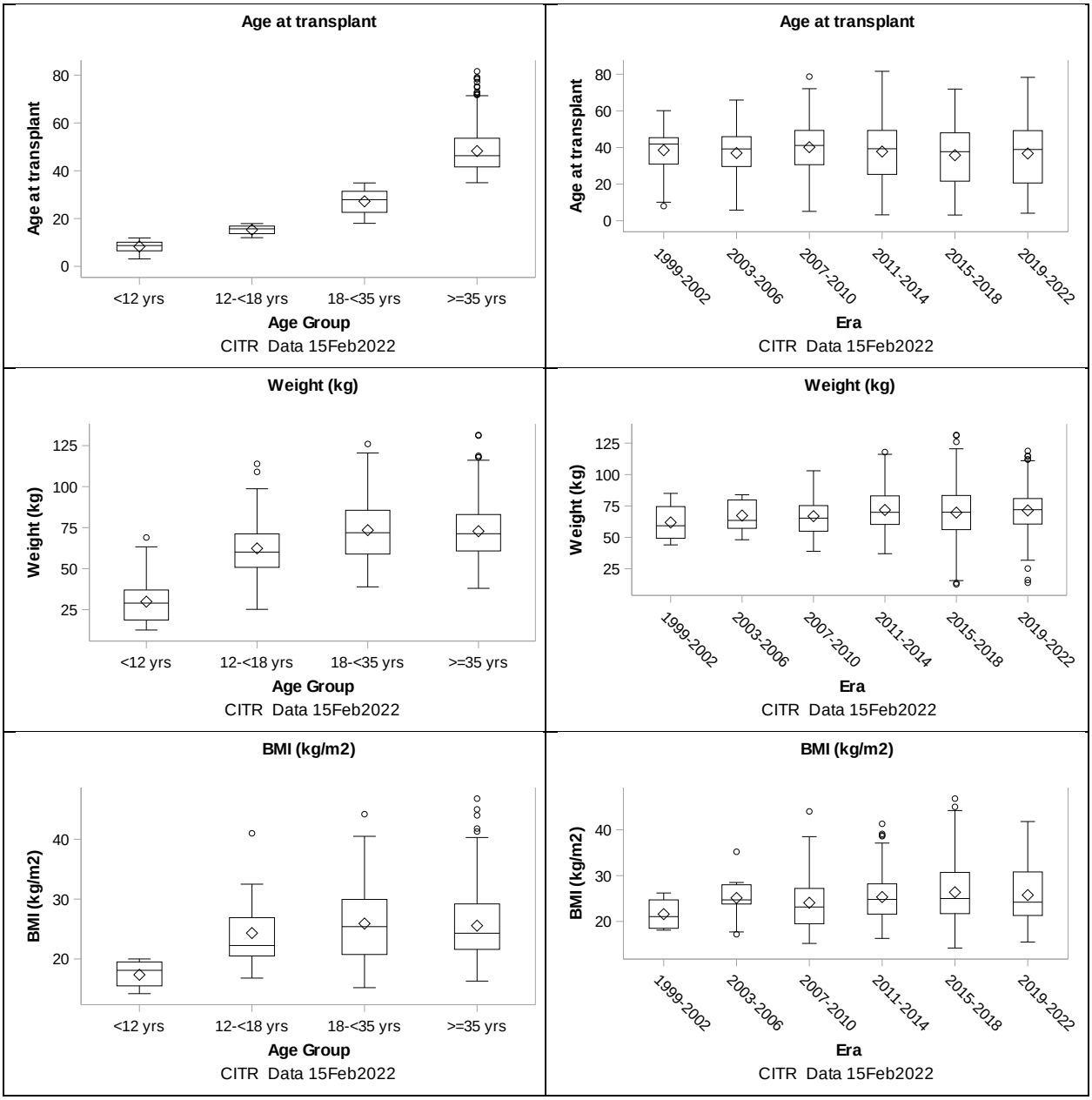


Exhibit 2 – 2A (continued)
Recipient Characteristics at First Infusion

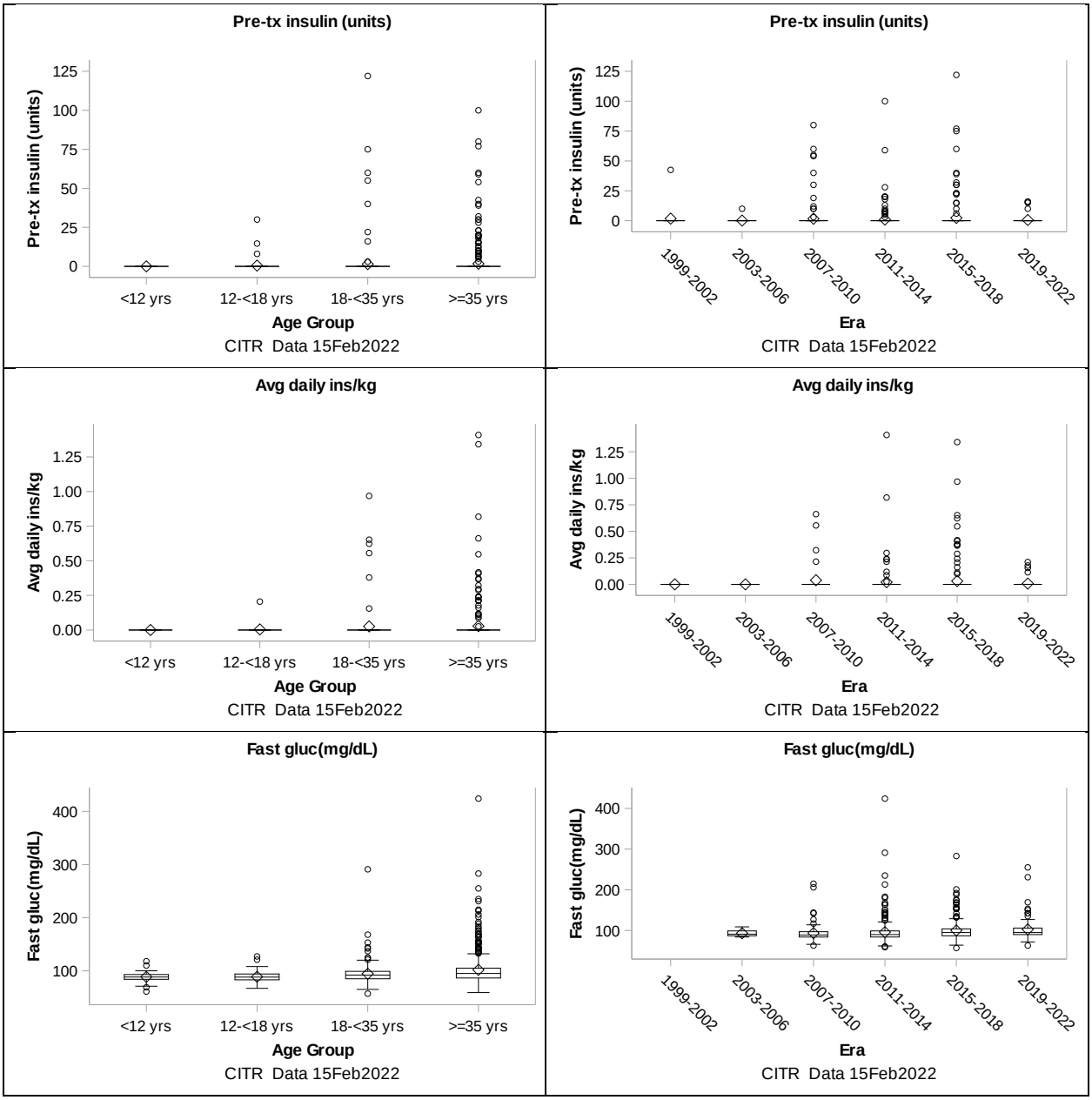


Exhibit 2 – 2A (continued)
Recipient Characteristics at First Infusion

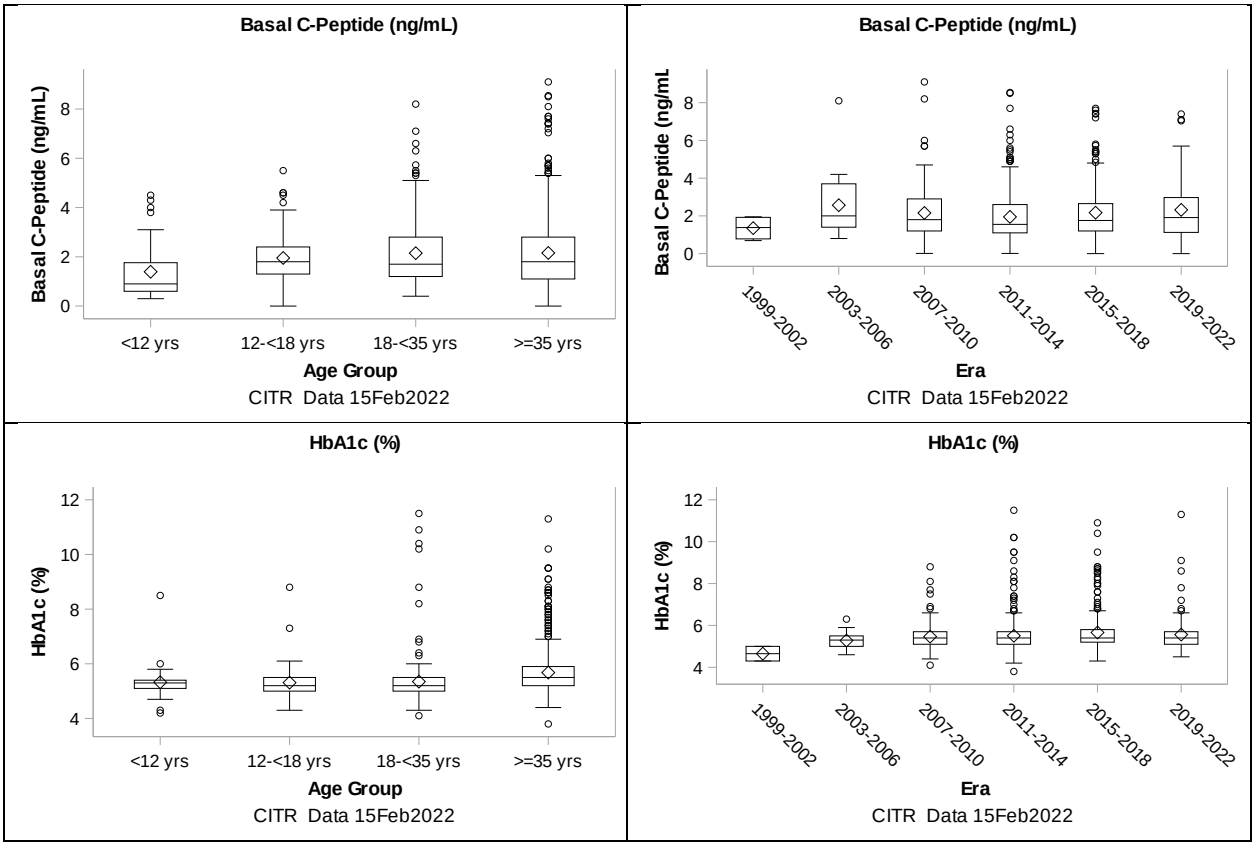


Exhibit 2 – 2B

Recipient Insulin Use at First Infusion

	Age group							
	<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs	
	N	%	N	%	N	%	N	%
Baseline Daily Insulin Use (Units)								
Not on insulin	60	100.0	104	97.2	264	97.1	564	93.5
On insulin	-	-	3	2.8	8	2.9	39	6.5

Available data	Age group							
	<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs	
	N	%	N	%	N	%	N	%
Baseline Daily Insulin Use (Units)								
Missing	6	9.1	9	7.8	42	13.4	134	18.2
Not on insulin	60	90.9	104	89.7	264	84.1	564	76.5
On insulin	-	-	3	2.6	8	2.5	39	5.3

	Era											
	1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022	
	N	%	N	%	N	%	N	%	N	%	N	%
Baseline Daily Insulin Use (Units)												
Not on insulin	23	95.8	77	98.7	212	95.1	346	95.3	245	93.9	89	95.7
On insulin	1	4.2	1	1.3	11	4.9	17	4.7	16	6.1	4	4.3

Available data	Era											
	1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022	
	N	%	N	%	N	%	N	%	N	%	N	%
Baseline Daily Insulin Use (Units)												
Missing	16	40.0	12	13.3	54	19.5	31	7.9	58	18.2	20	17.7
Not on insulin	23	57.5	77	85.6	212	76.5	346	87.8	245	76.8	89	78.8
On insulin	1	2.5	1	1.1	11	4.0	17	4.3	16	5.0	4	3.5

Exhibit 2 – 3

Recipient Characteristics and Medical History

		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Hypoglycemia status	**Having episodes and aware**	0	0.0	1	2.9	1	0.9	11	3.2	
	No Occurrence	15	100.0	34	97.1	112	97.4	324	95.6	**
	Unawareness	0	0.0	0	0.0	2	1.7	4	1.2	

Data Completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Hypoglycemia status	Available	15	22.7	35	30.2	115	36.6	339	46.0	
	Missing	51	77.3	81	69.8	199	63.4	398	54.0	

		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	p
Hypoglycemia status	**Having episodes and aware**	0	0.0	0	0.0	2	2.5	3	1.2	7	6.1	1	2.6	***
	No Occurrence	4	100.0	12	100.0	79	97.5	245	96.5	107	93.9	38	97.4	
	Unawareness	0	0.0	0	0.0	0	0.0	6	2.4	0	0.0	0	0.0	

Data completeness		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
Hypoglycemia status	Available	4	10.0	12	13.3	81	29.2	254	64.5	114	35.7	39	34.5	
	Missing	36	90.0	78	86.7	196	70.8	140	35.5	205	64.3	74	65.5	

		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Severe Hypoglycemic Events	**ASHE**	43	100.0	87	96.7	247	100.0	589	99.2	*
	SHE	0	0.0	3	3.3	0	0.0	5	0.8	

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Severe Hypoglycemic Events	Missing	23	34.8	26	22.4	67	21.3	143	19.4	
	Available	43	65.2	90	77.6	247	78.7	594	80.6	

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

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

		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	p
Severe Hypoglycemic Events	**ASHE**	37	100.0	87	100.0	260	99.6	372	99.7	137	96.5	73	98.6	*
	SHE	0	0.0	0	0.0	1	0.4	1	0.3	5	3.5	1	1.4	

Data completeness		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
Severe Hypoglycemic Events	Missing	3	7.5	3	3.3	16	5.8	21	5.3	177	55.5	39	34.5	
	Available	37	92.5	87	96.7	261	94.2	373	94.7	142	44.5	74	65.5	

		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Lipid-lowering medication	**No**	6	100.0	19	100.0	85	98.8	225	84.3	***
	Yes	0	0.0	0	0.0	1	1.2	42	15.7	

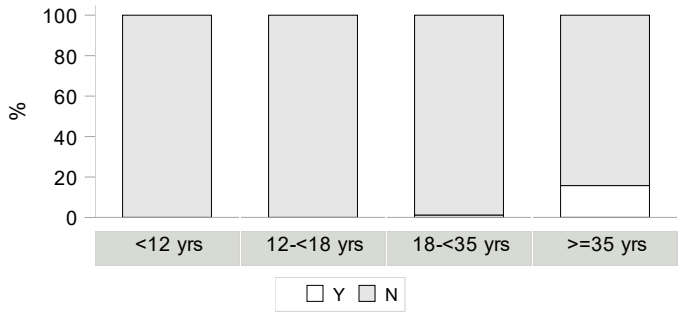
Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Lipid-lowering medication	Missing	60	90.9	97	83.6	228	72.6	470	63.8	
	Available	6	9.1	19	16.4	86	27.4	267	36.2	

		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	p
Lipid-lowering medication	**No**	4	100.0	2	66.7	37	78.7	151	88.3	104	92.0	37	92.5	
	Yes	0	0.0	1	33.3	10	21.3	20	11.7	9	8.0	3	7.5	

Data completeness		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
Lipid-lowering medication	Missing	36	90.0	87	96.7	230	83.0	223	56.6	206	64.6	73	64.6	
	Available	4	10.0	3	3.3	47	17.0	171	43.4	113	35.4	40	35.4	

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

Exhibit 2 – 3 (continued)
Recipient Characteristics and Medical History
Lipid-lowering medication



CITR Data 15Feb2022

		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		p
		N	%	N	%	N	%	N	%	
Anti-hypertension medication	**No**	6	100.0	19	95.0	83	95.4	200	74.1	***
	Yes	0	0.0	1	5.0	4	4.6	70	25.9	

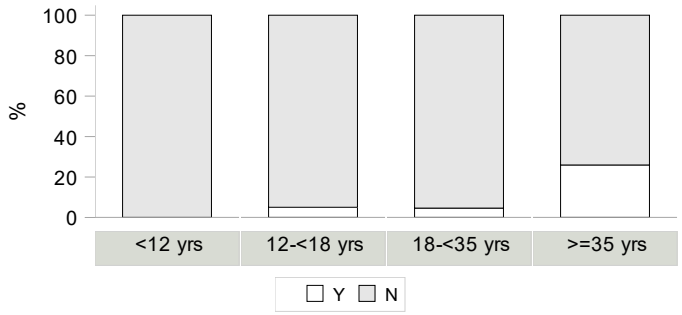
Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Anti-hypertension medication	Missing	60	90.9	96	82.8	227	72.3	467	63.4	
	Available	6	9.1	20	17.2	87	27.7	270	36.6	

		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		p
		N	%	N	%	N	%	N	%	N	%	N	%	
Anti-hypertension medication	**No**	4	100.0	2	66.7	37	78.7	131	75.7	98	84.5	36	90.0	
	Yes	0	0.0	1	33.3	10	21.3	42	24.3	18	15.5	4	10.0	

Data completeness		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
Anti-hypertension medication	Missing	36	90.0	87	96.7	230	83.0	221	56.1	203	63.6	73	64.6	
	Available	4	10.0	3	3.3	47	17.0	173	43.9	116	36.4	40	35.4	

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

Exhibit 2 – 3 (continued)
Recipient Characteristics and Medical History
Anti-hypertension medication



CITR Data 15Feb2022

		Age Group								p
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Anti-hyperglycemia medication	**No**	5	100.0	19	95.0	83	94.3	247	89.8	
	Yes	0	0.0	1	5.0	5	5.7	28	10.2	

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Anti-hyperglycemia medication	Missing	61	92.4	96	82.8	226	72.0	462	62.7	
	Available	5	7.6	20	17.2	88	28.0	275	37.3	

		Era												p
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
Anti-hyperglycemia medication	**No**	4	100.0	3	100.0	46	95.8	159	89.8	103	91.2	39	90.7	
	Yes	0	0.0	0	0.0	2	4.2	18	10.2	10	8.8	4	9.3	

Data completeness		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
Anti-hyperglycemia medication	Missing	36	90.0	87	96.7	229	82.7	217	55.1	206	64.6	70	61.9	
	Available	4	10.0	3	3.3	48	17.3	177	44.9	113	35.4	43	38.1	

		Age Group								p
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Smoker	**No**	9	100.0	22	95.7	83	83.8	234	72.4	**
	Yes	0	0.0	1	4.3	16	16.2	89	27.6	

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

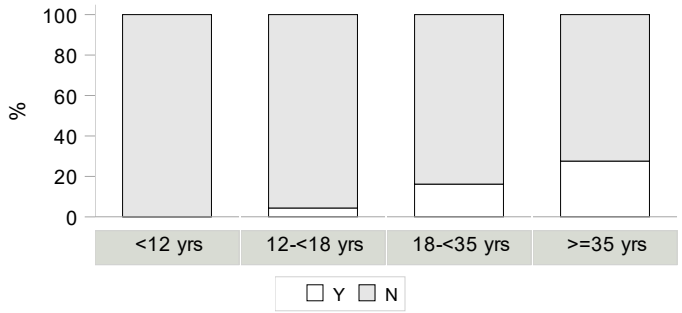
Exhibit 2 – 3 (continued)
Recipient Characteristics and Medical History

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Smoker	Missing	57	86.4	93	80.2	215	68.5	414	56.2	
	Available	9	13.6	23	19.8	99	31.5	323	43.8	

		Era												p
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
Smoker	No	1	50.0	9	75.0	56	65.1	139	78.5	106	79.7	37	84.1	
	Yes	1	50.0	3	25.0	30	34.9	38	21.5	27	20.3	7	15.9	

Data completeness		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
Smoker	Missing	38	95.0	78	86.7	191	69.0	217	55.1	186	58.3	69	61.1	
	Available	2	5.0	12	13.3	86	31.0	177	44.9	133	41.7	44	38.9	

Smoker



CITR Data 15Feb2022

		Age Group								p
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
CAD history	No	5	100.0	17	94.4	81	100.0	278	94.9	
	Yes	0	0.0	1	5.6	0	0.0	15	5.1	

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
CAD history	Missing	61	92.4	98	84.5	233	74.2	444	60.2	
	Available	5	7.6	18	15.5	81	25.8	293	39.8	

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

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

		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	p
CAD history	No	4	100.0	12	100.0	82	97.6	142	94.0	105	96.3	36	97.3	
	Yes	0	0.0	0	0.0	2	2.4	9	6.0	4	3.7	1	2.7	

Data completeness		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
CAD history	Missing	36	90.0	78	86.7	193	69.7	243	61.7	210	65.8	76	67.3	
	Available	4	10.0	12	13.3	84	30.3	151	38.3	109	34.2	37	32.7	

		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
CVA history	No	5	100.0	18	100.0	82	100.0	286	97.3	
	Yes	0	0.0	0	0.0	0	0.0	8	2.7	

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
CVA history	Missing	61	92.4	98	84.5	232	73.9	443	60.1	
	Available	5	7.6	18	15.5	82	26.1	294	39.9	

		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	p
CVA history	No	4	100.0	11	91.7	82	96.5	147	97.4	110	100.0	37	100.0	
	Yes	0	0.0	1	8.3	3	3.5	4	2.6	0	0.0	0	0.0	

Data completeness		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
CVA history	Missing	36	90.0	78	86.7	192	69.3	243	61.7	209	65.5	76	67.3	
	Available	4	10.0	12	13.3	85	30.7	151	38.3	110	34.5	37	32.7	

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

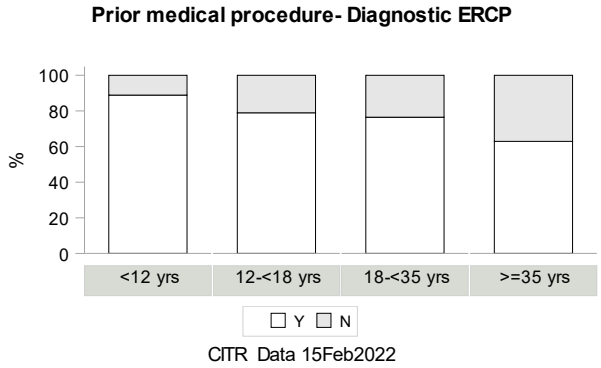
Exhibit 2 – 3 (continued)
Recipient Characteristics and Medical History

		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Prior medical procedure- Diagnostic ERCP	**No**	1	11.1	8	21.1	32	23.5	141	37.1	**
	Yes	8	88.9	30	78.9	104	76.5	239	62.9	

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Prior medical procedure- Diagnostic ERCP	Missing	57	86.4	78	67.2	178	56.7	357	48.4	
	Available	9	13.6	38	32.8	136	43.3	380	51.6	

		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	p
Prior medical procedure- Diagnostic ERCP	**No**	3	100.0	5	50.0	48	20.0	51	34.5	49	40.8	26	61.9	***
	Yes	0	0.0	5	50.0	192	80.0	97	65.5	71	59.2	16	38.1	

Data completeness		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
Prior medical procedure- Diagnostic ERCP	Missing	37	92.5	80	88.9	37	13.4	246	62.4	199	62.4	71	62.8	
	Available	3	7.5	10	11.1	240	86.6	148	37.6	120	37.6	42	37.2	



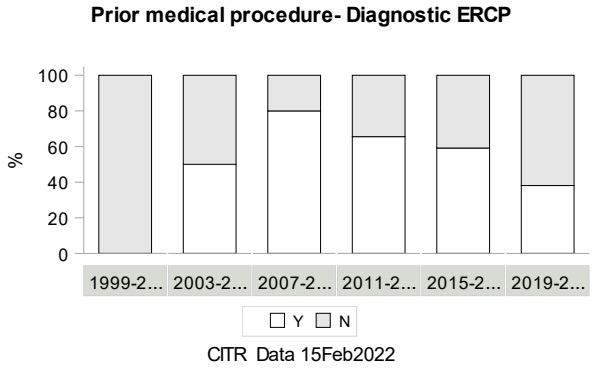


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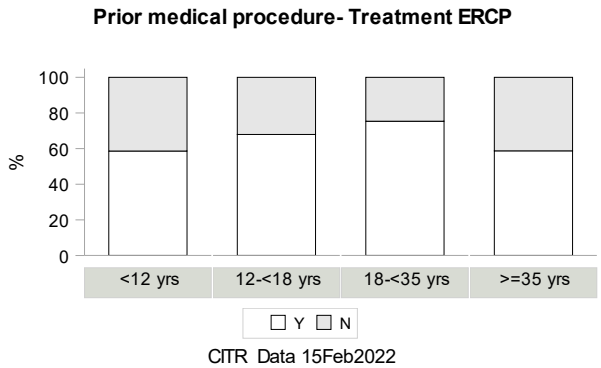
Exhibit 2 – 3 (continued)
Recipient Characteristics and Medical History

		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Prior medical procedure- Treatment ERCP	**No**	12	41.4	17	32.1	34	24.6	156	41.3	**
	Yes	17	58.6	36	67.9	104	75.4	222	58.7	

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Prior medical procedure- Treatment ERCP	Missing	37	56.1	63	54.3	176	56.1	359	48.7	
	Available	29	43.9	53	45.7	138	43.9	378	51.3	

		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	p
Prior medical procedure- Treatment ERCP	**No**	3	100.0	6	85.7	42	50.0	65	39.6	70	28.1	33	36.3	***
	Yes	0	0.0	1	14.3	42	50.0	99	60.4	179	71.9	58	63.7	

Data completeness		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
Prior medical procedure- Treatment ERCP	Missing	37	92.5	83	92.2	193	69.7	230	58.4	70	21.9	22	19.5	
	Available	3	7.5	7	7.8	84	30.3	164	41.6	249	78.1	91	80.5	



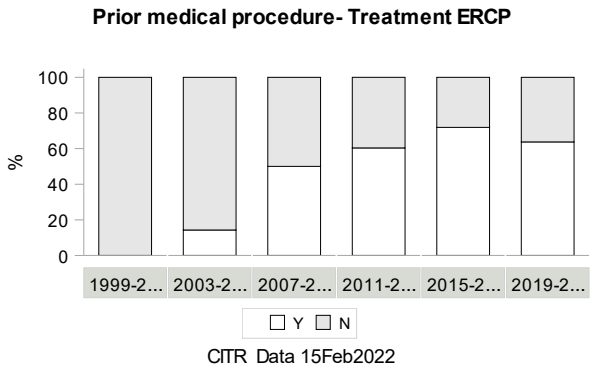


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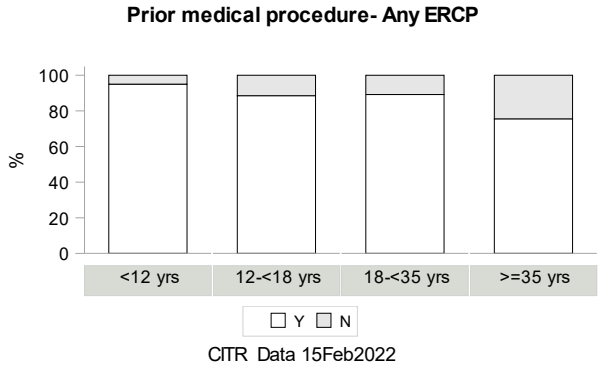
Exhibit 2 – 3 (continued)
Recipient Characteristics and Medical History

		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Prior medical procedure- Any ERCP	**No**	1	5.0	7	11.5	21	10.8	116	24.5	***
	Yes	19	95.0	54	88.5	173	89.2	358	75.5	

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Prior medical procedure- Any ERCP	Missing	46	69.7	55	47.4	120	38.2	263	35.7	
	Available	20	30.3	61	52.6	194	61.8	474	64.3	

		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	p
Prior medical procedure- Any ERCP	**No**	3	100.0	5	50.0	35	14.2	47	27.2	34	14.5	21	25.6	***
	Yes	0	0.0	5	50.0	211	85.8	126	72.8	201	85.5	61	74.4	

Data completeness		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
Prior medical procedure- Any ERCP	Missing	37	92.5	80	88.9	31	11.2	221	56.1	84	26.3	31	27.4	
	Available	3	7.5	10	11.1	246	88.8	173	43.9	235	73.7	82	72.6	



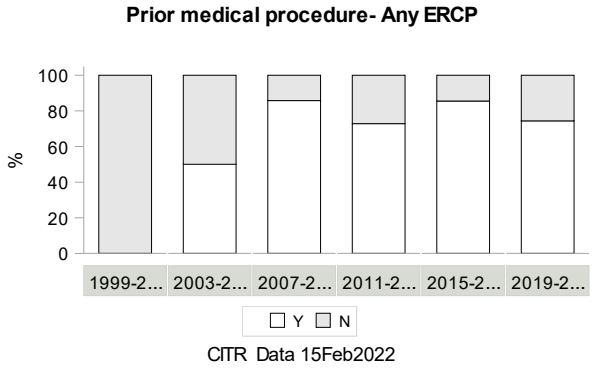


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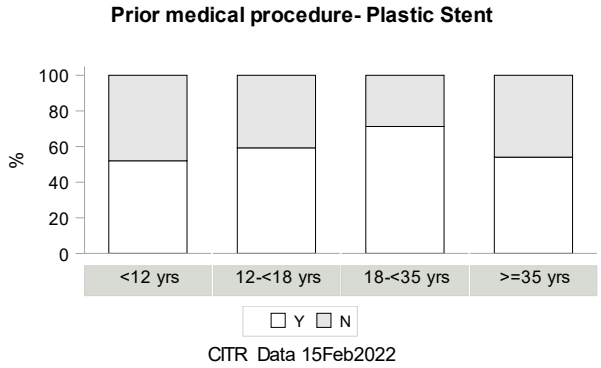
Exhibit 2 – 3 (continued)
Recipient Characteristics and Medical History

		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Prior medical procedure- Plastic Stent	**No**	12	48.0	22	40.7	46	28.8	182	46.0	**
	Yes	13	52.0	32	59.3	114	71.3	214	54.0	

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Prior medical procedure- Plastic Stent	Missing	41	62.1	62	53.4	154	49.0	341	46.3	
	Available	25	37.9	54	46.6	160	51.0	396	53.7	

		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	p
Prior medical procedure- Plastic Stent	**No**	3	100.0	8	80.0	48	23.4	73	67.6	91	41.4	39	43.8	***
	Yes	0	0.0	2	20.0	157	76.6	35	32.4	129	58.6	50	56.2	

Data completeness		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
Prior medical procedure- Plastic Stent	Missing	37	92.5	80	88.9	72	26.0	286	72.6	99	31.0	24	21.2	
	Available	3	7.5	10	11.1	205	74.0	108	27.4	220	69.0	89	78.8	



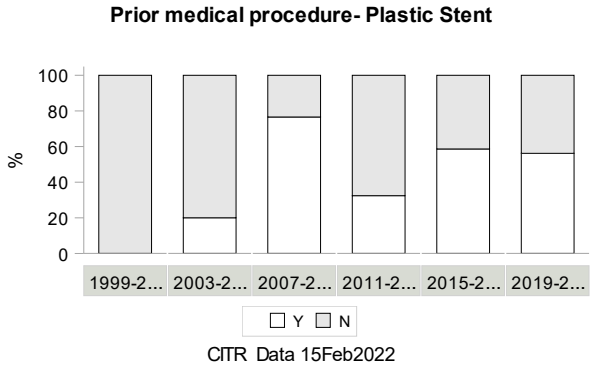


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Exhibit 2 – 3 (continued)
Recipient Characteristics and Medical History

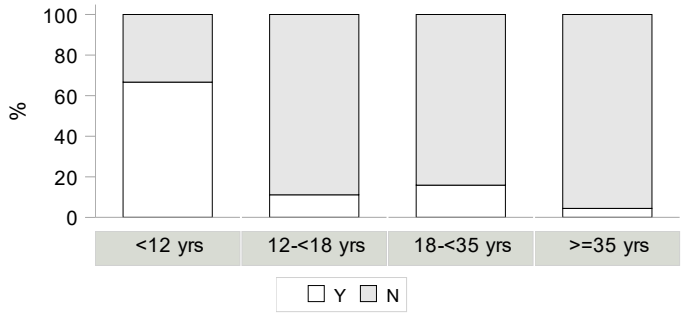
		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Prior medical procedure- Metal Stent	**No**	1	33.3	16	88.9	53	84.1	217	95.6	***
	Yes	2	66.7	2	11.1	10	15.9	10	4.4	

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Prior medical procedure- Metal Stent	Missing	63	95.5	98	84.5	251	79.9	510	69.2	
	Available	3	4.5	18	15.5	63	20.1	227	30.8	

		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	p
Prior medical procedure- Metal Stent	**No**	3	100.0	9	100.0	62	92.5	96	89.7	80	92.0	37	97.4	
	Yes	0	0.0	0	0.0	5	7.5	11	10.3	7	8.0	1	2.6	

Data completeness		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
Prior medical procedure- Metal Stent	Missing	37	92.5	81	90.0	210	75.8	287	72.8	232	72.7	75	66.4	
	Available	3	7.5	9	10.0	67	24.2	107	27.2	87	27.3	38	33.6	

Prior medical procedure- Metal Stent



CITR Data 15Feb2022

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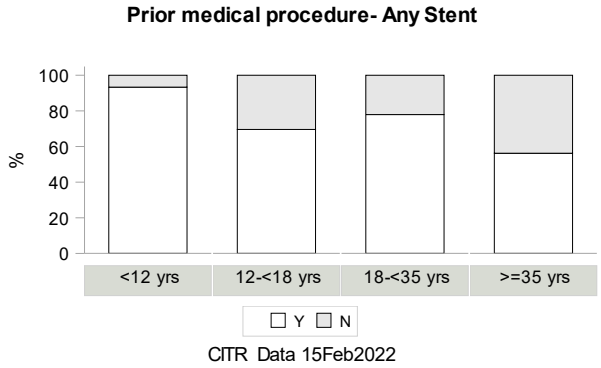
Exhibit 2 – 3 (continued)
Recipient Characteristics and Medical History

		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Prior medical procedure- Any Stent	**No**	1	6.7	14	30.4	34	22.1	169	43.8	***
	Yes	14	93.3	32	69.6	120	77.9	217	56.2	

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Prior medical procedure- Any Stent	Missing	51	77.3	70	60.3	160	51.0	351	47.6	
	Available	15	22.7	46	39.7	154	49.0	386	52.4	

		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	p
Prior medical procedure- Any Stent	**No**	3	100.0	8	80.0	48	23.4	73	62.4	60	31.7	26	33.8	***
	Yes	0	0.0	2	20.0	157	76.6	44	37.6	129	68.3	51	66.2	

Data completeness		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
Prior medical procedure- Any Stent	Missing	37	92.5	80	88.9	72	26.0	277	70.3	130	40.8	36	31.9	
	Available	3	7.5	10	11.1	205	74.0	117	29.7	189	59.2	77	68.1	



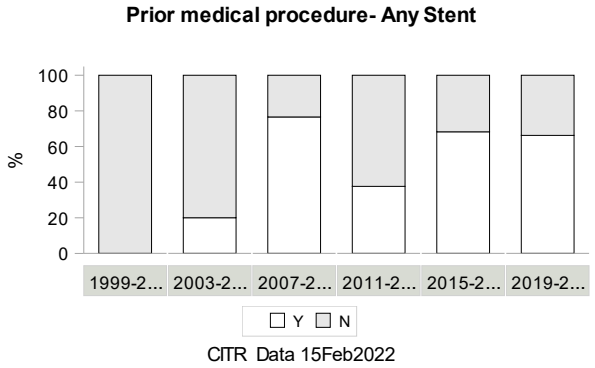


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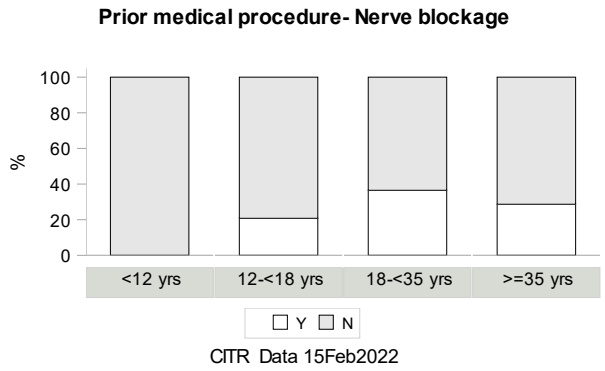
Exhibit 2 – 3 (continued)
Recipient Characteristics and Medical History

		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Prior medical procedure- Nerve blockage	**No**	28	100.0	42	79.2	101	63.5	294	71.4	***
	Yes	0	0.0	11	20.8	58	36.5	118	28.6	

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Prior medical procedure- Nerve blockage	Missing	38	57.6	63	54.3	155	49.4	325	44.1	
	Available	28	42.4	53	45.7	159	50.6	412	55.9	

		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	p
Prior medical procedure- Nerve blockage	**No**	3	42.9	11	52.4	74	56.9	125	75.8	179	74.9	73	81.1	***
	Yes	4	57.1	10	47.6	56	43.1	40	24.2	60	25.1	17	18.9	

Data completeness		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
Prior medical procedure- Nerve blockage	Missing	33	82.5	69	76.7	147	53.1	229	58.1	80	25.1	23	20.4	
	Available	7	17.5	21	23.3	130	46.9	165	41.9	239	74.9	90	79.6	



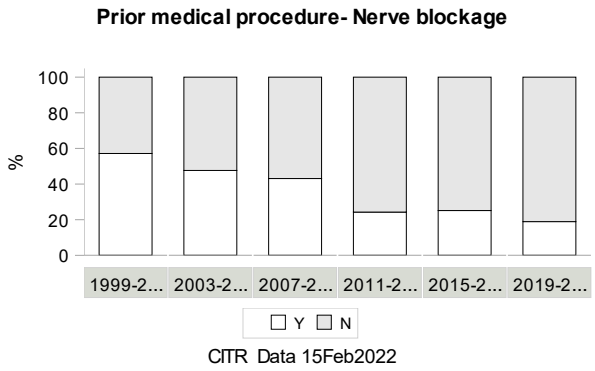


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Exhibit 2 – 3 (continued)
Recipient Characteristics and Medical History

		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Prior medical procedure- Drainage	**No**	5	83.3	16	76.2	75	92.6	264	87.7	
	Yes	1	16.7	5	23.8	6	7.4	37	12.3	

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Prior medical procedure- Drainage	Missing	60	90.9	95	81.9	233	74.2	436	59.2	
	Available	6	9.1	21	18.1	81	25.8	301	40.8	

		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	p
Prior medical procedure- Drainage	**No**	3	50.0	11	78.6	67	73.6	149	94.9	100	96.2	30	81.1	***
	Yes	3	50.0	3	21.4	24	26.4	8	5.1	4	3.8	7	18.9	

Data completeness		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
Prior medical procedure- Drainage	Missing	34	85.0	76	84.4	186	67.1	237	60.2	215	67.4	76	67.3	
	Available	6	15.0	14	15.6	91	32.9	157	39.8	104	32.6	37	32.7	

Prior medical procedure- Drainage

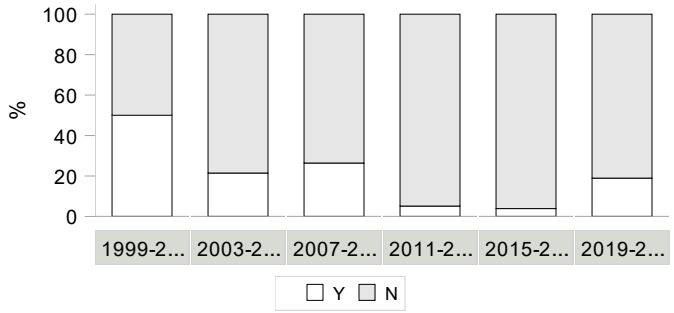

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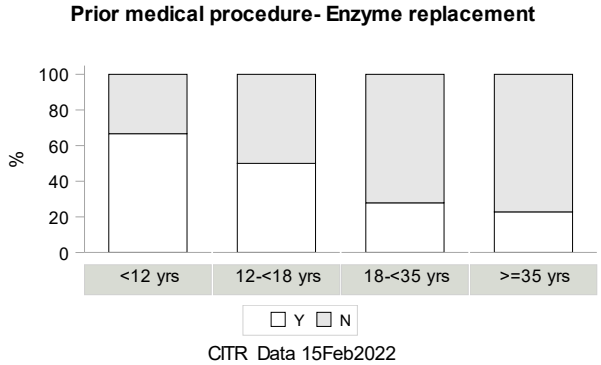
Exhibit 2 – 3 (continued)
Recipient Characteristics and Medical History

		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Prior medical procedure- Enzyme replacement	**No**	2	33.3	9	50.0	57	72.2	234	77.2	**
	Yes	4	66.7	9	50.0	22	27.8	69	22.8	

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Prior medical procedure- Enzyme replacement	Missing	60	90.9	98	84.5	235	74.8	434	58.9	
	Available	6	9.1	18	15.5	79	25.2	303	41.1	

		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	p
Prior medical procedure- Enzyme replacement	**No**	3	100.0	7	58.3	62	77.5	123	78.8	86	74.8	21	52.5	*
	Yes	0	0.0	5	41.7	18	22.5	33	21.2	29	25.2	19	47.5	

Data completeness		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
Prior medical procedure- Enzyme replacement	Missing	37	92.5	78	86.7	197	71.1	238	60.4	204	63.9	73	64.6	
	Available	3	7.5	12	13.3	80	28.9	156	39.6	115	36.1	40	35.4	



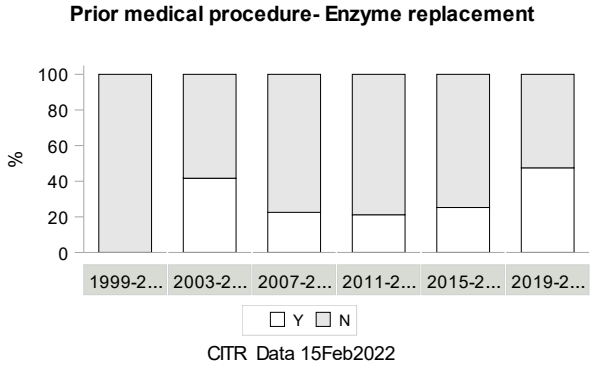


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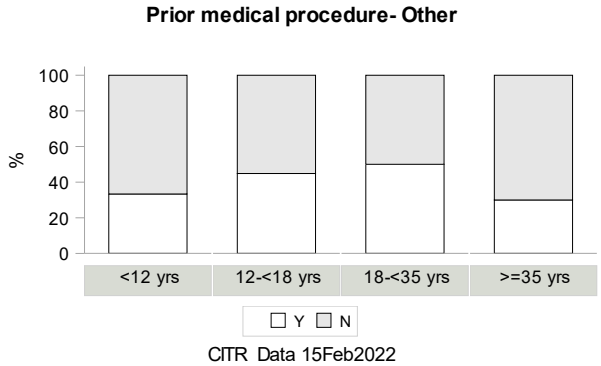
Exhibit 2 – 3 (continued)
Recipient Characteristics and Medical History

		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Prior medical procedure- Other	**No**	6	66.7	16	55.2	66	50.0	264	70.0	***
	Yes	3	33.3	13	44.8	66	50.0	113	30.0	

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Prior medical procedure- Other	Missing	57	86.4	87	75.0	182	58.0	360	48.8	
	Available	9	13.6	29	25.0	132	42.0	377	51.2	

		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	p
Prior medical procedure- Other	**No**	3	75.0	11	84.6	58	25.8	145	94.8	98	87.5	37	92.5	***
	Yes	1	25.0	2	15.4	167	74.2	8	5.2	14	12.5	3	7.5	

Data completeness		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
Prior medical procedure- Other	Missing	36	90.0	77	85.6	52	18.8	241	61.2	207	64.9	73	64.6	
	Available	4	10.0	13	14.4	225	81.2	153	38.8	112	35.1	40	35.4	



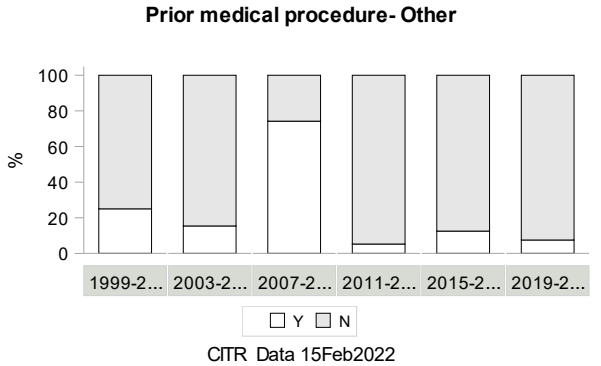


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Exhibit 2 – 3 (continued)
Recipient Characteristics and Medical History

		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Prior surgical procedure- Frey	No	27	100.0	52	98.1	143	96.6	391	99.2	
	Yes		0.0	1	1.9	5	3.4	3	0.8	

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Prior surgical procedure- Frey	Missing	39	59.1	63	54.3	166	52.9	343	46.5	
	Available	27	40.9	53	45.7	148	47.1	394	53.5	

		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	p
Prior surgical procedure- Frey	No	3	75.0	12	100.0	87	98.9	172	98.9	248	98.0	91	100.0	
	Yes	1	25.0		0.0	1	1.1	2	1.1	5	2.0		0.0	

Data completeness		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
Prior surgical procedure- Frey	Missing	36	90.0	78	86.7	189	68.2	220	55.8	66	20.7	22	19.5	
	Available	4	10.0	12	13.3	88	31.8	174	44.2	253	79.3	91	80.5	

		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Prior surgical procedure- Puestow	No	27	93.1	50	90.9	142	92.2	379	94.3	
	Yes	2	6.9	5	9.1	12	7.8	23	5.7	

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Prior surgical procedure- Puestow	Missing	37	56.1	61	52.6	160	51.0	335	45.5	
	Available	29	43.9	55	47.4	154	49.0	402	54.5	

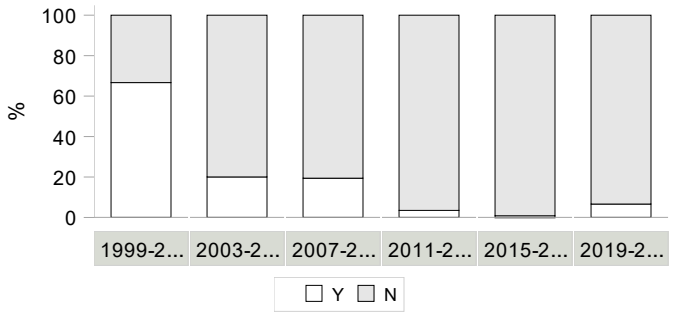
*=p<.05; **=p<.01; ***=p<.001

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

		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	p
Prior surgical procedure- Puestow	**No**	3	33.3	12	80.0	79	80.6	168	96.6	251	99.2	85	93.4	***
	Yes	6	66.7	3	20.0	19	19.4	6	3.4	2	0.8	6	6.6	

Data completeness		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
Prior surgical procedure- Puestow	Missing	31	77.5	75	83.3	179	64.6	220	55.8	66	20.7	22	19.5	
	Available	9	22.5	15	16.7	98	35.4	174	44.2	253	79.3	91	80.5	

Prior surgical procedure- Puestow



		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Prior surgical procedure- Traveral	**No**	5	100.0	23	100.0	98	100.0	314	100.0	

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Prior surgical procedure- Traveral	Missing	61	92.4	93	80.2	216	68.8	423	57.4	
	Available	5	7.6	23	19.8	98	31.2	314	42.6	

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

		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	p
Prior surgical procedure- Traveral	**No**	3	100.0	12	100.0	85	100.0	174	100.0	124	100.0	42	100.0	

Data completeness		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
Prior surgical procedure- Traveral	Missing	37	92.5	78	86.7	192	69.3	220	55.8	195	61.1	71	62.8	
	Available	3	7.5	12	13.3	85	30.7	174	44.2	124	38.9	42	37.2	

		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Prior surgical procedure- partial pancreatectomy	**No**	27	100.0	52	98.1	143	94.7	378	94.3	
	Yes	0	0.0	1	1.9	8	5.3	23	5.7	

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Prior surgical procedure- partial pancreatectomy	Missing	39	59.1	63	54.3	163	51.9	336	45.6	
	Available	27	40.9	53	45.7	151	48.1	401	54.4	

		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	p
Prior surgical procedure- partial pancreatectomy	**No**	3	60.0	11	64.7	79	88.8	168	96.0	251	98.4	88	96.7	***
	Yes	2	40.0	6	35.3	10	11.2	7	4.0	4	1.6	3	3.3	

Data completeness		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
Prior surgical procedure- partial pancreatectomy	Missing	35	87.5	73	81.1	188	67.9	219	55.6	64	20.1	22	19.5	
	Available	5	12.5	17	18.9	89	32.1	175	44.4	255	79.9	91	80.5	

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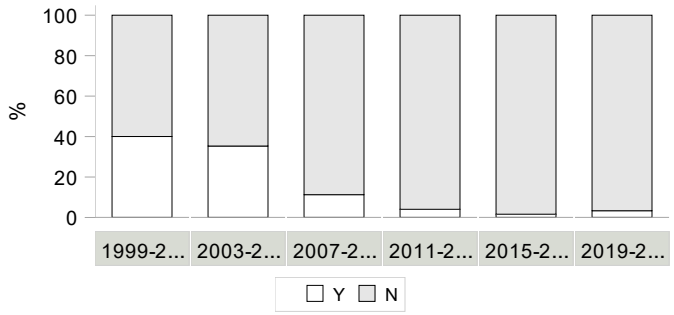
Exhibit 2 – 3 (continued)
Recipient Characteristics and Medical History
Prior surgical procedure- Partial pancreatectomy



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		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Prior surgical procedure- Other	**No**	5	100.0	19	52.8	72	45.0	241	55.7	*
	Yes	0	0.0	17	47.2	88	55.0	192	44.3	

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Prior surgical procedure- Other	Missing	61	92.4	80	69.0	154	49.0	304	41.2	
	Available	5	7.6	36	31.0	160	51.0	433	58.8	

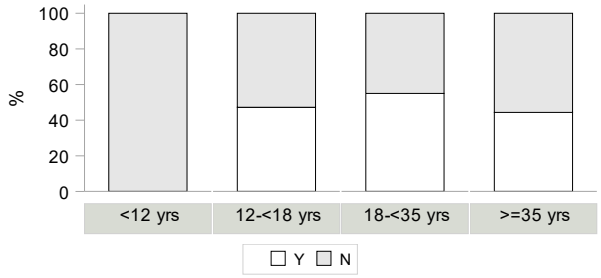
		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	p
Prior surgical procedure- Other	**No**	4	33.3	12	20.7	66	29.2	134	77.9	87	70.2	34	81.0	***
	Yes	8	66.7	46	79.3	160	70.8	38	22.1	37	29.8	8	19.0	

Data completeness		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
Prior surgical procedure- Other	Missing	28	70.0	32	35.6	51	18.4	222	56.3	195	61.1	71	62.8	
	Available	12	30.0	58	64.4	226	81.6	172	43.7	124	38.9	42	37.2	

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

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

Prior surgical procedure- Other



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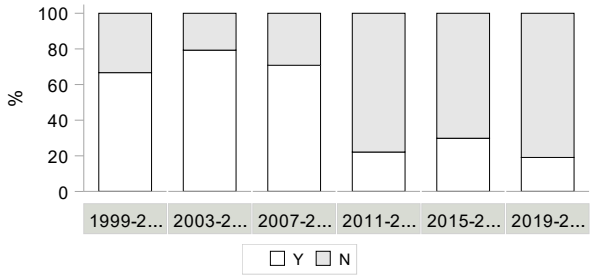
Prior surgical procedure- Other



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		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Pancreatectomy performed	**Yes**	65	100.0	116	100.0	303	100.0	693	100.0	

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Pancreatectomy performed	Missing	1	1.5	0	0.0	11	3.5	44	6.0	
	Available	65	98.5	116	100.0	303	96.5	693	94.0	

		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	p
Pancreatectomy performed	**Yes**	40	100.0	89	100.0	265	100.0	387	100.0	299	100.0	97	100.0	

Data completeness		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
Pancreatectomy performed	Missing	0	0.0	1	1.1	12	4.3	7	1.8	20	6.3	16	14.2	
	Available	40	100.0	89	98.9	265	95.7	387	98.2	299	93.7	97	85.8	

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

Exhibit 2 – 4

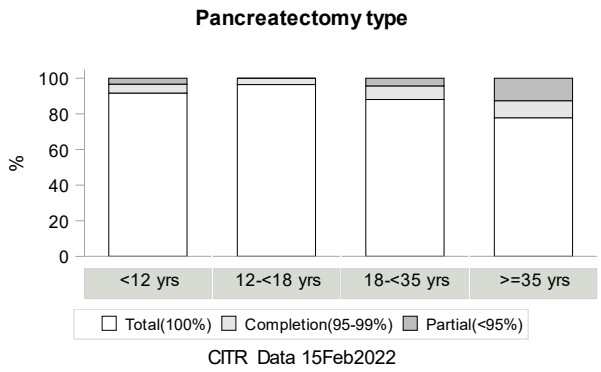
Recipient Pancreatectomy Information

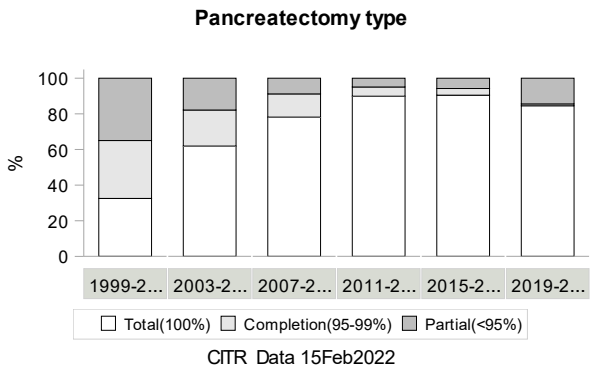
		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Pancreatectomy type	Total(100%)	55	91.7	108	96.4	265	88.0	536	77.8	
	Completion(95-99%)	3	5.0	4	3.6	23	7.6	66	9.6	***
	Partial(<95%)	2	3.3	0	0.0	13	4.3	87	12.6	

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Pancreatectomy type	Missing	6	9.1	4	3.4	13	4.1	48	6.5	
	Available	60	90.9	112	96.6	301	95.9	689	93.5	

		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	p
Pancreatectomy type	Total(100%)	13	32.5	52	61.9	204	78.2	347	89.9	266	90.5	82	84.5	
	Completion (95-99%)	13	32.5	17	20.2	34	13.0	20	5.2	11	3.7	1	1.0	***
	Partial(<95%)	14	35.0	15	17.9	23	8.8	19	4.9	17	5.8	14	14.4	

Data completeness		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
Pancreatectomy type	Missing	0	0.0	6	6.7	16	5.8	8	2.0	25	7.8	16	14.2	
	Available	40	100.0	84	93.3	261	94.2	386	98.0	294	92.2	97	85.8	





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

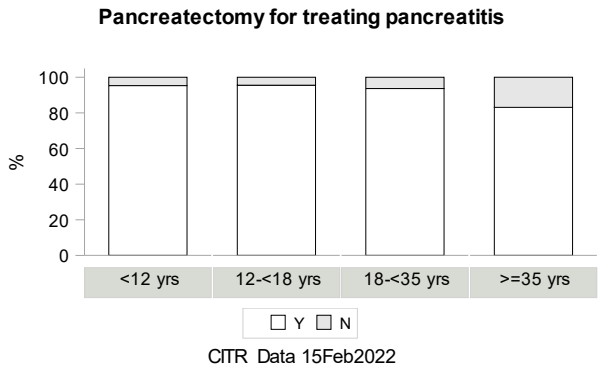
Exhibit 2 – 4 (continued)
Recipient Pancreatectomy Information

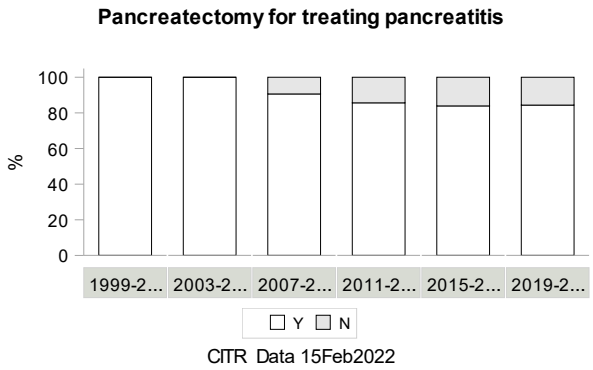
		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Pancreatectomy for treating pancreatitis	**No**	3	4.7	5	4.5	19	6.3	114	16.9	***
	Yes	61	95.3	107	95.5	281	93.7	560	83.1	

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Pancreatectomy for treating pancreatitis	Missing	2	3.0	4	3.4	14	4.5	63	8.5	
	Available	64	97.0	112	96.6	300	95.5	674	91.5	

		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	p
Pancreatectomy for treating pancreatitis	**No**	0	0.0	0	0.0	24	9.4	55	14.4	47	16.1	15	15.6	***
	Yes	38	100.0	85	100.0	232	90.6	328	85.6	245	83.9	81	84.4	

Data completeness		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
Pancreatectomy for treating pancreatitis	Missing	2	5.0	5	5.6	21	7.6	11	2.8	27	8.5	17	15.0	
	Available	38	95.0	85	94.4	256	92.4	383	97.2	292	91.5	96	85.0	





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

Exhibit 2 – 4 (continued)
Recipient Pancreatectomy Information

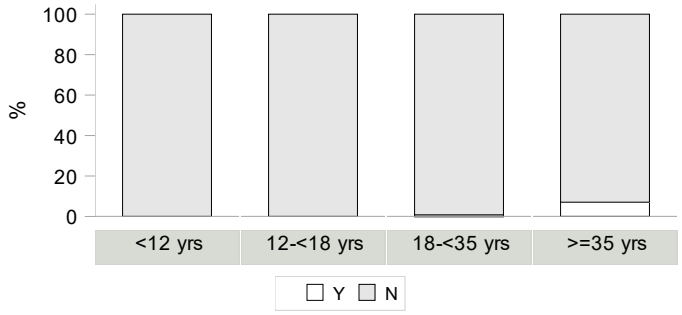
		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Pancreatectomy for treating cancer	**No**	60	100.0	98	100.0	262	99.2	571	93.0	***
	Yes	0	0.0	0	0.0	2	0.8	43	7.0	

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Pancreatectomy for treating cancer	Missing	6	9.1	18	15.5	50	15.9	123	16.7	
	Available	60	90.9	98	84.5	264	84.1	614	83.3	

		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	p
Pancreatectomy for treating cancer	**No**	36	100.0	78	100.0	204	94.4	354	94.4	274	96.8	45	93.8	
	Yes	0	0.0	0	0.0	12	5.6	21	5.6	9	3.2	3	6.3	

Data completeness		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
Pancreatectomy for treating cancer	Missing	4	10.0	12	13.3	61	22.0	19	4.8	36	11.3	65	57.5	
	Available	36	90.0	78	86.7	216	78.0	375	95.2	283	88.7	48	42.5	

Pancreatectomy for treating cancer



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

Exhibit 2 – 4 (continued)
Recipient Pancreatectomy Information

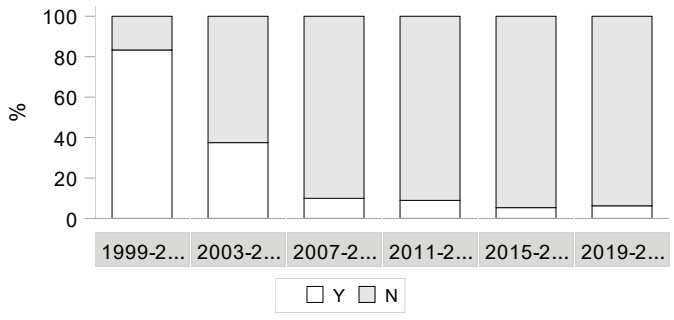
		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Pancreatectomy for treating pancreatic pseudocysts	**No**	31	83.8	59	93.7	162	92.0	414	91.6	
	Yes	6	16.2	4	6.3	14	8.0	38	8.4	

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Pancreatectomy for treating pancreatic pseudocysts	Missing	29	43.9	53	45.7	138	43.9	285	38.7	
	Available	37	56.1	63	54.3	176	56.1	452	61.3	

		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	p
Pancreatectomy for treating pancreatic pseudocysts	**No**	1	16.7	5	62.5	145	90.1	204	91.1	266	94.7	45	93.8	***
	Yes	5	83.3	3	37.5	16	9.9	20	8.9	15	5.3	3	6.3	

Data completeness		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
Pancreatectomy for treating pancreatic pseudocysts	Missing	34	85.0	82	91.1	116	41.9	170	43.1	38	11.9	65	57.5	
	Available	6	15.0	8	8.9	161	58.1	224	56.9	281	88.1	48	42.5	

Pancreatectomy for treating pancreatic pseudocysts



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

Exhibit 2 – 4 (continued)
Recipient Pancreatectomy Information

		Age Group								p
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Pancreatectomy for treating pancreatic cysts	**No**	59	100.0	98	100.0	264	100.0	605	98.5	
	Yes	0	0.0	0	0.0	0	0.0	9	1.5	

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Pancreatectomy for treating pancreatic cysts	Missing	7	10.6	18	15.5	50	15.9	123	16.7	
	Available	59	89.4	98	84.5	264	84.1	614	83.3	

		Era												p
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
Pancreatectomy for treating pancreatic cysts	**No**	36	100.0	78	100.0	214	99.5	372	99.2	281	99.3	45	93.8	
	Yes	0	0.0	0	0.0	1	0.5	3	0.8	2	0.7	3	6.3	

Data completeness		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
Pancreatectomy for treating pancreatic cysts	Missing	4	10.0	12	13.3	62	22.4	19	4.8	36	11.3	65	57.5	
	Available	36	90.0	78	86.7	215	77.6	375	95.2	283	88.7	48	42.5	

		Age Group								p
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Pancreatectomy for treating tumors	**No**	59	100.0	98	100.0	261	98.9	594	96.7	
	Yes	0	0.0	0	0.0	3	1.1	20	3.3	

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Pancreatectomy for treating tumors	Missing	7	10.6	18	15.5	50	15.9	123	16.7	
	Available	59	89.4	98	84.5	264	84.1	614	83.3	

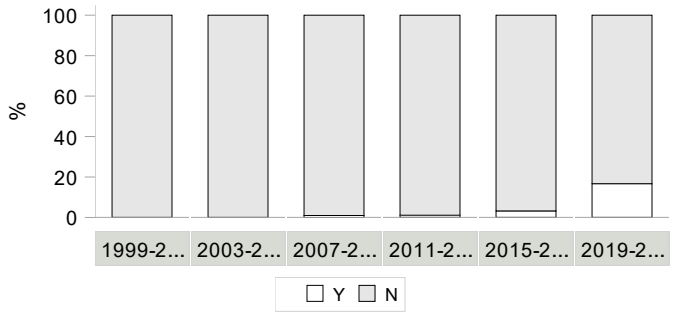
*=p<.05; **=p<.01; ***=p<.001

Exhibit 2 – 4 (continued)
Recipient Pancreatectomy Information

		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	p
Pancreatectomy for treating tumors	**No**	36	100.0	78	100.0	214	99.1	371	98.9	273	96.8	40	83.3	***
	Yes	0	0.0	0	0.0	2	0.9	4	1.1	9	3.2	8	16.7	

Data completeness		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
Pancreatectomy for treating tumors	Missing	4	10.0	12	13.3	61	22.0	19	4.8	37	11.6	65	57.5	
	Available	36	90.0	78	86.7	216	78.0	375	95.2	282	88.4	48	42.5	

Pancreatectomy for treating tumors



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		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Pancreatectomy for treating chronic pancreatitis	**No**	2	3.1	10	8.9	24	9.0	89	14.8	**
	Yes	62	96.9	102	91.1	243	91.0	512	85.2	

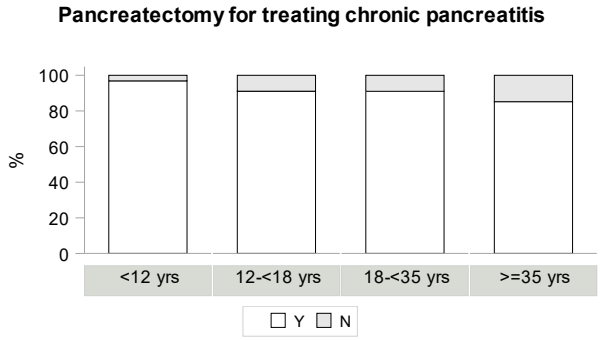
Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Pancreatectomy for treating chronic pancreatitis	Missing	2	3.0	4	3.4	47	15.0	136	18.5	
	Available	64	97.0	112	96.6	267	85.0	601	81.5	

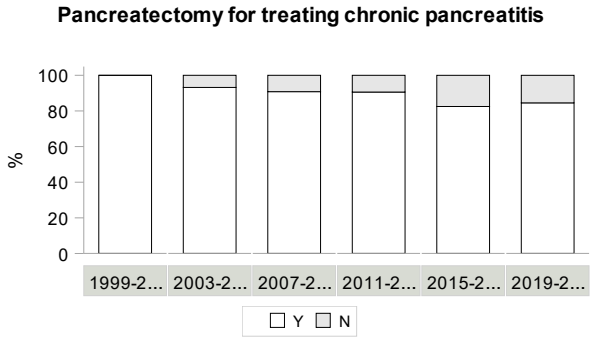
*=p<.05; **=p<.01; ***=p<.001

Exhibit 2 – 4 (continued)
Recipient Pancreatectomy Information

		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	p
Pancreatectomy for treating chronic pancreatitis	**No**		0.0	3	6.8	19	9.2	36	9.4	52	17.5	15	15.5	**
	Yes	16	100.0	41	93.2	188	90.8	347	90.6	245	82.5	82	84.5	

Data completeness		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
Pancreatectomy for treating chronic pancreatitis	Missing	24	60.0	46	51.1	70	25.3	11	2.8	22	6.9	16	14.2	
	Available	16	40.0	44	48.9	207	74.7	383	97.2	297	93.1	97	85.8	





		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Pancreatectomy for treating acute pancreatitis	**No**	5	8.3	25	23.1	76	29.5	271	46.8	***
	Yes	55	91.7	83	76.9	182	70.5	308	53.2	

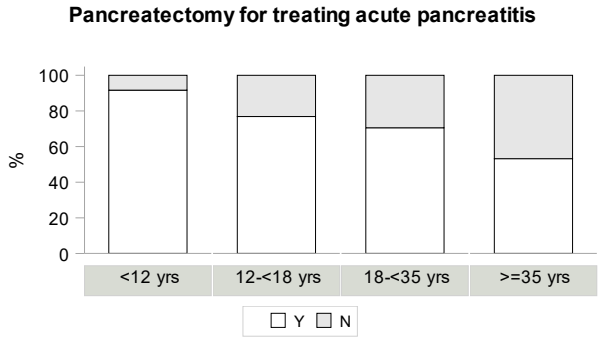
Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Pancreatectomy for treating acute pancreatitis	Missing	6	9.1	8	6.9	56	17.8	158	21.4	
	Available	60	90.9	108	93.1	258	82.2	579	78.6	

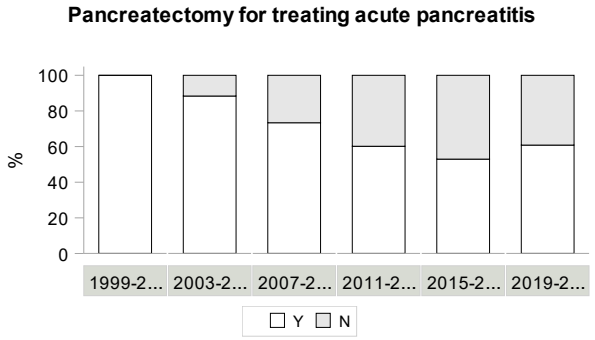
*=p<.05; **=p<.01; ***=p<.001

Exhibit 2 – 4 (continued)
Recipient Pancreatectomy Information

		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	p
Pancreatectomy for treating acute pancreatitis	**No**	0	0.0	5	11.6	53	26.6	145	39.8	136	47.1	38	39.2	***
	Yes	13	100.0	38	88.4	146	73.4	219	60.2	153	52.9	59	60.8	

Data completeness		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
Pancreatectomy for treating acute pancreatitis	Missing	27	67.5	47	52.2	78	28.2	30	7.6	30	9.4	16	14.2	
	Available	13	32.5	43	47.8	199	71.8	364	92.4	289	90.6	97	85.8	





		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Pancreatectomy for treating trauma	**No**	59	100.0	97	99.0	258	97.7	612	99.5	
	Yes	0	0.0	1	1.0	6	2.3	3	0.5	

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Pancreatectomy for treating trauma	Missing	7	10.6	18	15.5	50	15.9	122	16.6	
	Available	59	89.4	98	84.5	264	84.1	615	83.4	

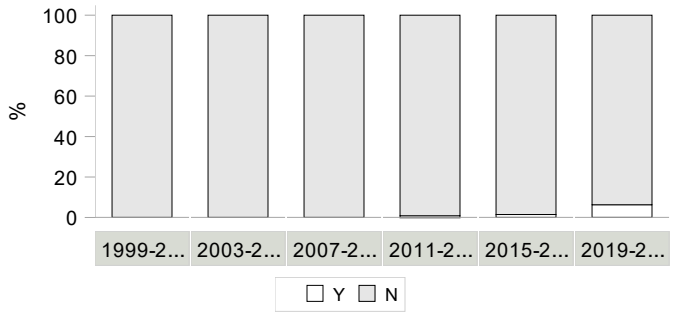
*=p<.05; **=p<.01; ***=p<.001

Exhibit 2 – 4 (continued)
Recipient Pancreatectomy Information

		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	p
Pancreatectomy for treating trauma	**No**	36	100.0	78	100.0	216	100.0	372	99.2	279	98.6	45	93.8	*
	Yes	0	0.0	0	0.0	0	0.0	3	0.8	4	1.4	3	6.3	

Data completeness		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
Pancreatectomy for treating trauma	Missing	4	10.0	12	13.3	61	22.0	19	4.8	36	11.3	65	57.5	
	Available	36	90.0	78	86.7	216	78.0	375	95.2	283	88.7	48	42.5	

Pancreatectomy for treating trauma



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		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Pancreatectomy for treating necrosis	**No**	37	100.0	61	98.4	174	98.9	443	97.4	
	Yes	0	0.0	1	1.6	2	1.1	12	2.6	

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Pancreatectomy for treating necrosis	Missing	29	43.9	54	46.6	138	43.9	282	38.3	
	Available	37	56.1	62	53.4	176	56.1	455	61.7	

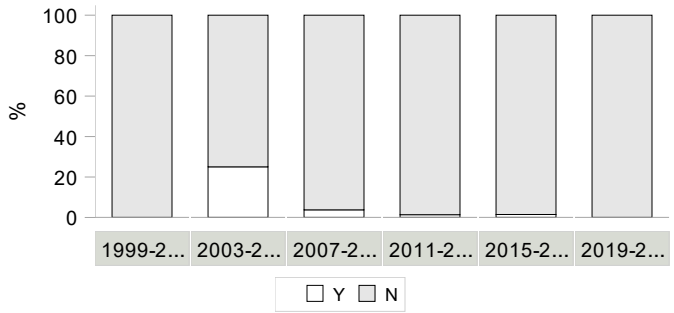
*=p<.05; **=p<.01; ***=p<.001

Exhibit 2 – 4 (continued)
Recipient Pancreatectomy Information

		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	p
Pancreatectomy for treating necrosis	**No**	6	100.0	6	75.0	155	96.3	223	98.7	277	98.6	48	100.0	*
	Yes	0	0.0	2	25.0	6	3.7	3	1.3	4	1.4	0	0.0	

Data completeness		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
Pancreatectomy for treating necrosis	Missing	34	85.0	82	91.1	116	41.9	168	42.6	38	11.9	65	57.5	
	Available	6	15.0	8	8.9	161	58.1	226	57.4	281	88.1	48	42.5	

Pancreatectomy for treating necrosis



		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	p
Pancreatectomy for treating infection	**No**	59	100.0	98	100.0	264	100.0	609	99.0	
	Yes	0	0.0	0	0.0	0	0.0	6	1.0	

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Pancreatectomy for treating infection	Missing	7	10.6	18	15.5	50	15.9	122	16.6	
	Available	59	89.4	98	84.5	264	84.1	615	83.4	

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

Exhibit 2 – 4 (continued)
Recipient Pancreatectomy Information

		Era												p
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
Pancreatectomy for treating infection	**No**	36	100.0	77	98.7	214	99.1	372	99.2	283	100.0	48	100.0	
	Yes	0	0.0	1	1.3	2	0.9	3	0.8	0	0.0	0	0.0	

Data completeness		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
Pancreatectomy for treating infection	Missing	4	10.0	12	13.3	61	22.0	19	4.8	36	11.3	65	57.5	
	Available	36	90.0	78	86.7	216	78.0	375	95.2	283	88.7	48	42.5	

		Age Group								p
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Pancreatectomy for treating Other	**No**	59	100.0	96	99.0	262	99.6	598	96.5	*
	Yes	0	0.0	1	1.0	1	0.4	22	3.5	

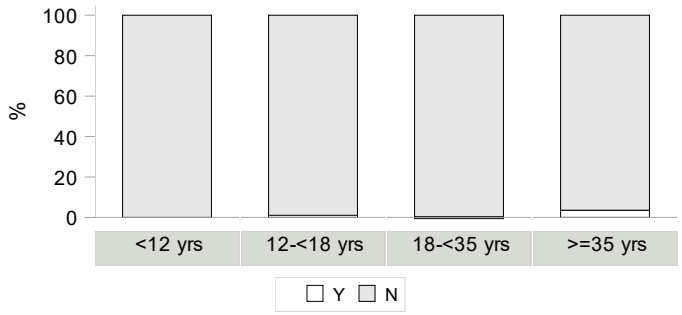
Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Pancreatectomy for treating Other	Missing	7	10.6	19	16.4	51	16.2	117	15.9	
	Available	59	89.4	97	83.6	263	83.8	620	84.1	

		Era												p
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
Pancreatectomy for treating Other	**No**	36	94.7	78	96.3	214	96.4	366	98.1	275	98.9	46	97.9	
	Yes	2	5.3	3	3.7	8	3.6	7	1.9	3	1.1	1	2.1	

Data completeness		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
Pancreatectomy for treating Other	Missing	2	5.0	9	10.0	55	19.9	21	5.3	41	12.9	66	58.4	
	Available	38	95.0	81	90.0	222	80.1	373	94.7	278	87.1	47	41.6	

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

Exhibit 2 – 4 (continued)
Recipient Pancreatectomy Information
Pancreatectomy for treating Other



CITR Data 15Feb2022

	Age Group												p
	<12 yrs			12-<18 yrs			18-<35 yrs			>=35 yrs			
	N	Mean	SE	N	Mean	SE	N	Mean	SE	N	Mean	SE	
Pancreatitis duration (yrs)	31	4.2	0.5	64	6.4	0.6	185	6.9	0.5	369	6.6	0.3	

	Era																		p
	1999-2002			2003-2006			2007-2010			2011-2014			2015-2018			2019-2022			
	N	Mean	SE	N	Mean	SE	N	Mean	SE	N	Mean	SE	N	Mean	SE	N	Mean	SE	
Pancreatitis duration (yrs)	29	6.8	0.9	70	7.3	0.7	202	6.7	0.4	258	6.0	0.4	63	7.2	0.7	27	6.6	1.6	

		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		p
		N	%	N	%	N	%	N	%	
Pancreatitis etiology	**Alcohol/Drug induced**	0	0.0	0	0.0	11	4.2	55	11.4	
	Biliary	0	0.0	0	0.0	6	2.3	16	3.3	
	Cystic Fibrosis	1	1.8	3	3.0	10	3.8	9	1.9	
	Idiopathic	7	12.7	16	16.2	79	30.4	169	34.9	
	Idiopathic (Pancreas divisum)	1	1.8	5	5.1	35	13.5	90	18.6	***
	Sphincter of Oddi Dysfunction (SOD)	0	0.0	2	2.0	31	11.9	72	14.9	
	Trauma	0	0.0	0	0.0	4	1.5	1	0.2	
	Familial	46	83.6	71	71.7	70	26.9	39	8.1	
	Other	0	0.0	2	2.0	14	5.4	33	6.8	

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

Exhibit 2 – 4 (continued)
Recipient Pancreatectomy Information

Data completeness		Age Group								
		<12 yrs		12-<18 yrs		18-<35 yrs		>=35 yrs		
		N	%	N	%	N	%	N	%	
Pancreatitis etiology	Missing	11	16.7	17	14.7	54	17.2	253	34.3	
	Available	55	83.3	99	85.3	260	82.8	484	65.7	

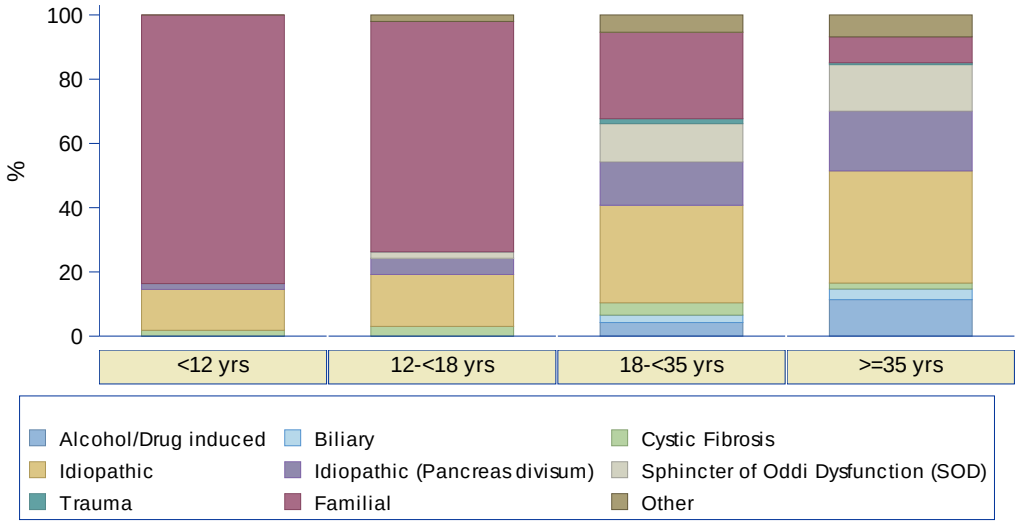
		Era												p
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
Pancreatitis etiology	**Alcohol/Drug induced**	7	20.6	10	14.1	11	5.0	16	5.5	12	5.8	10	13.5	***
	Biliary	3	8.8	2	2.8	7	3.2	5	1.7	4	1.9	1	1.4	
	Cystic Fibrosis	1	2.9	2	2.8	11	5.0	4	1.4	4	1.9	1	1.4	
	Idiopathic	13	38.2	37	52.1	86	38.7	65	22.5	52	25.0	18	24.3	
	Idiopathic (Pancreas divisum)	8	23.5	8	11.3	32	14.4	42	14.5	29	13.9	12	16.2	
	Sphincter of Oddi Dysfunction (SOD)	0	0.0	7	9.9	43	19.4	41	14.2	13	6.3	1	1.4	
	Trauma	0	0.0	0	0.0	0	0.0	4	1.4	1	0.5	0	0.0	
	Familial	2	5.9	3	4.2	21	9.5	88	30.4	83	39.9	29	39.2	
	Other	0	0.0	2	2.8	11	5.0	24	8.3	10	4.8	2	2.7	

Data completeness		Era												
		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
Pancreatitis etiology	Missing	6	15.0	19	21.1	55	19.9	105	26.6	111	34.8	39	34.5	
	Available	34	85.0	71	78.9	222	80.1	289	73.4	208	65.2	74	65.5	

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

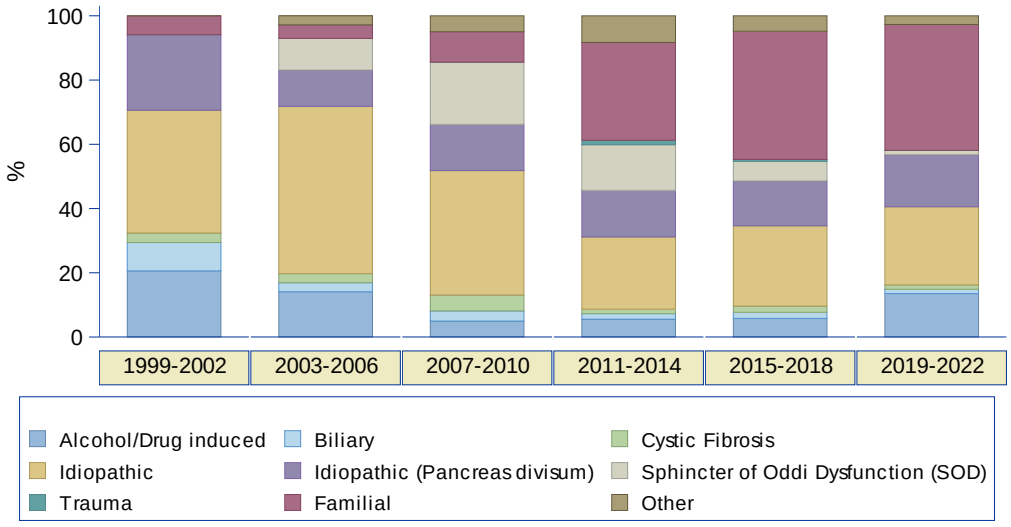
Exhibit 2 – 4 (continued)
Recipient Pancreatectomy Information

Pancreatitis etiology



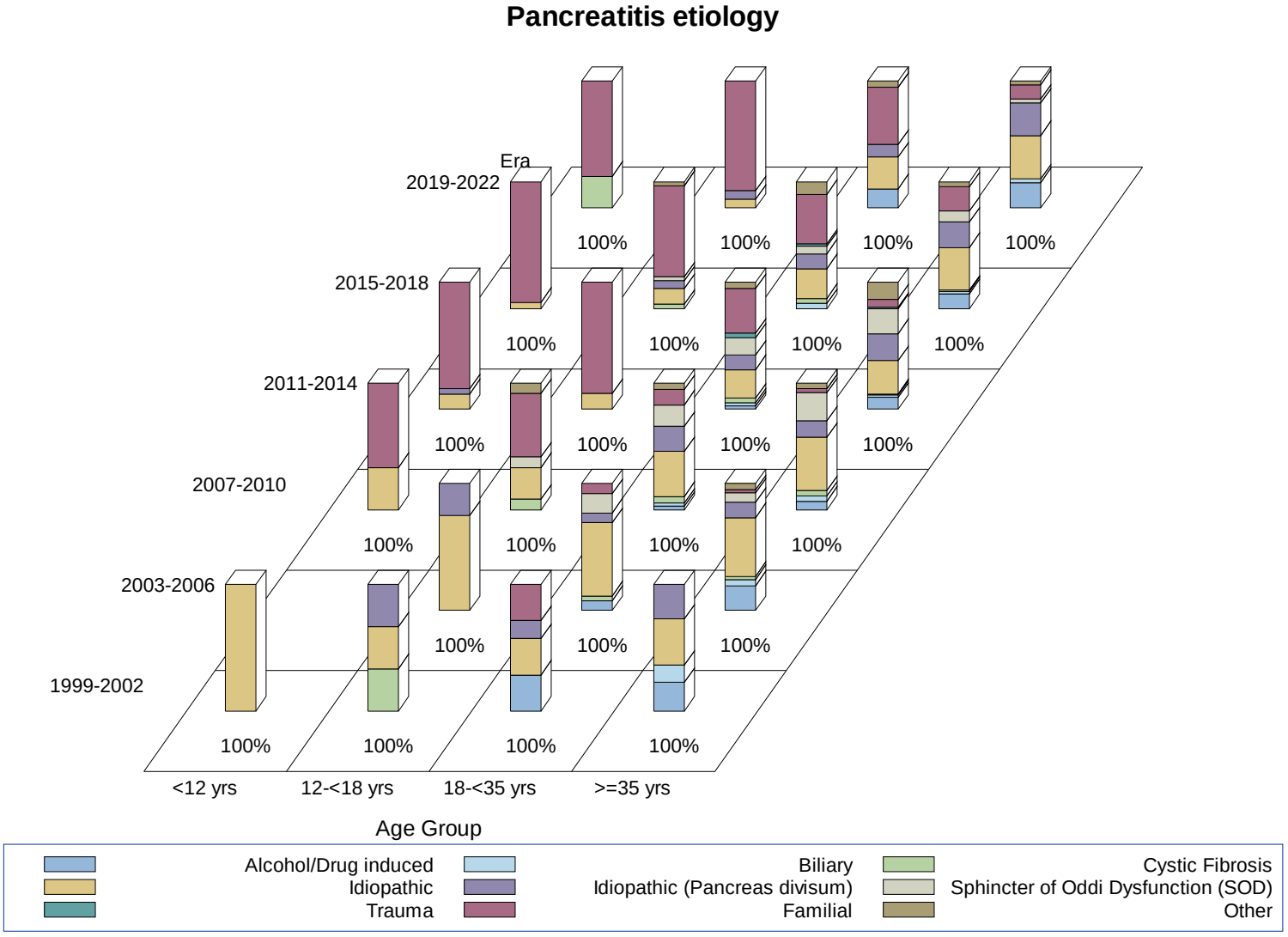
CITR Data 15Feb2022

Pancreatitis etiology



CITR Data 15Feb2022

Exhibit 2 – 4 (continued)
Recipient Pancreatectomy Information



CITR Data 15Feb2022

Exhibit 2 – 5

Recipient Laboratory Values at First Infusion

	Age Group												
	<12 yrs			12-<18 yrs			18-<35 yrs			>=35 yrs			
	N	Mean	SE	N	Mean	SE	N	Mean	SE	N	Mean	SE	p
HbA1c (%)	56	5.33	0.07	87	5.31	0.06	228	5.35	0.06	535	5.68	0.04	***
Basal C-Peptide (ng/mL)	48	1.39	0.16	81	1.95	0.12	222	2.15	0.09	517	2.16	0.07	**
Fasting blood glucose (mg/dL)	49	88.60	1.33	84	88.82	1.07	201	94.41	1.39	443	101.81	1.48	***
ALT (U/L)	50	28.62	3.59	82	39.09	4.98	236	37.43	2.21	603	37.42	1.71	
AST (U/L)	49	31.96	1.63	79	34.95	3.36	234	33.49	1.61	602	35.02	1.53	
Alkaline phosphatase (U/L)	50	229.44	10.28	82	149.06	8.72	233	84.38	2.34	593	99.08	2.93	***
Total bilirubin (mg/dL)	50	0.34	0.02	81	0.51	0.05	237	0.51	0.02	597	0.57	0.03	*
Total cholesterol (mg/dL)	1	134.00	-	7	135.86	8.66	37	163.32	6.68	97	179.60	4.56	*
HDL (mg/dL)	1	38.00	-	6	49.83	6.68	36	46.50	2.71	94	47.78	1.69	
LDL (mg/dL)	1	90.00	-	6	56.50	11.22	35	91.09	6.33	80	106.11	4.30	**
Triglycerides (mg/dL)	1	28.00	-	7	83.29	16.17	37	133.81	14.38	107	121.32	7.06	
Serum creatinine (mg/dL)	25	0.41	0.02	54	0.72	0.09	169	0.83	0.04	464	0.80	0.01	***
eGFR-CKD (mL/min/1.73m^2)	25	174.43	5.13	54	135.74	3.44	169	111.67	1.64	464	94.55	0.85	***

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

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

	Era																		
	1999-2002			2003-2006			2007-2010			2011-2014			2015-2018			2019-2022			
	N	Mean	SE	N	Mean	SE	N	Mean	SE	N	Mean	SE	N	Mean	SE	N	Mean	SE	p
HbA1c (%)	2	4.65	0.35	361	5.51	0.04	361	5.51	0.04	361	5.51	0.04	254	5.66	0.06	90	5.56	0.10	*
Basal C-Peptide (ng/mL)	4	1.35	0.33	363	1.95	0.07	363	1.95	0.07	363	1.95	0.07	216	2.17	0.10	92	2.32	0.17	
Fasting blood glucose (mg/dL)	0	-	-	331	96.06	1.58	331	96.06	1.58	331	96.06	1.58	234	100.24	1.65	86	102.74	3.04	*
ALT (U/L)	4	81.75	32.59	362	37.23	2.17	362	37.23	2.17	362	37.23	2.17	284	34.23	1.59	51	47.22	9.23	*
AST (U/L)	4	36.50	9.04	362	32.04	1.44	362	32.04	1.44	362	32.04	1.44	279	31.92	1.91	51	41.33	7.37	
Alkaline phosphatase (U/L)	4	97.75	33.50	360	109.24	4.13	360	109.24	4.13	360	109.24	4.13	282	105.13	4.46	47	105.81	17.81	
Total bilirubin (mg/dL)	4	0.56	0.17	360	0.55	0.04	360	0.55	0.04	360	0.55	0.04	283	0.55	0.03	51	0.63	0.08	
Total cholesterol (mg/dL)	2	193.00	50.00	40	176.78	5.81	40	176.78	5.81	40	176.78	5.81	59	174.32	5.77	32	160.75	7.75	
HDL (mg/dL)	2	44.50	9.50	38	44.71	2.74	38	44.71	2.74	38	44.71	2.74	58	47.97	1.83	30	49.13	3.18	
LDL (mg/dL)	0	-	-	33	102.06	4.25	33	102.06	4.25	33	102.06	4.25	52	103.02	5.39	29	87.90	7.64	
Triglycerides (mg/dL)	3	75.67	31.69	47	142.17	12.99	47	142.17	12.99	47	142.17	12.99	57	109.11	8.41	34	117.82	9.62	*
Serum creatinine (mg/dL)	4	0.76	0.05	189	0.81	0.02	189	0.81	0.02	189	0.81	0.02	258	0.76	0.02	102	0.82	0.06	
eGFR-CKD (mL/min/1.73m^2)	4	111.91	2.42	189	99.62	1.61	189	99.62	1.61	189	99.62	1.61	258	109.28	1.88	102	110.21	3.01	***

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

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

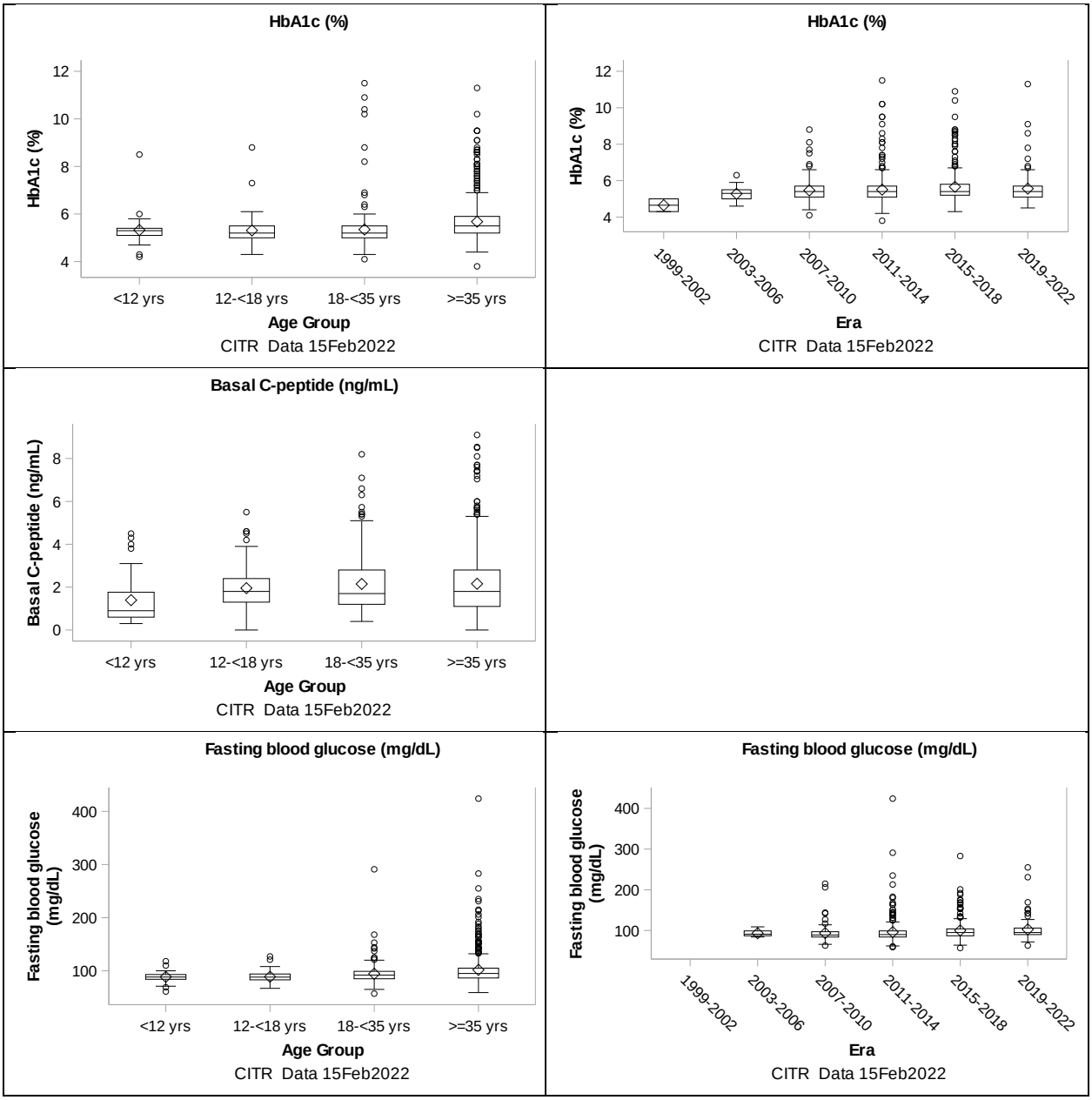
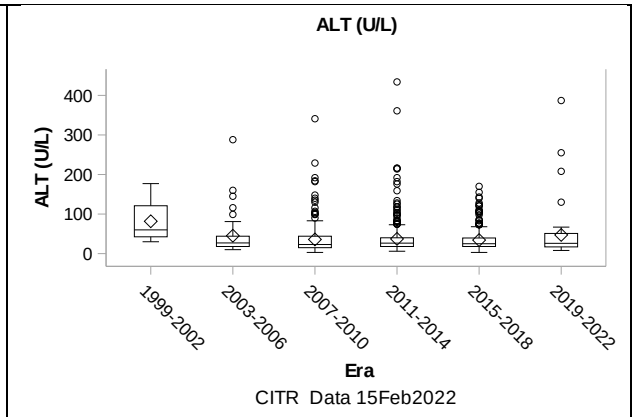
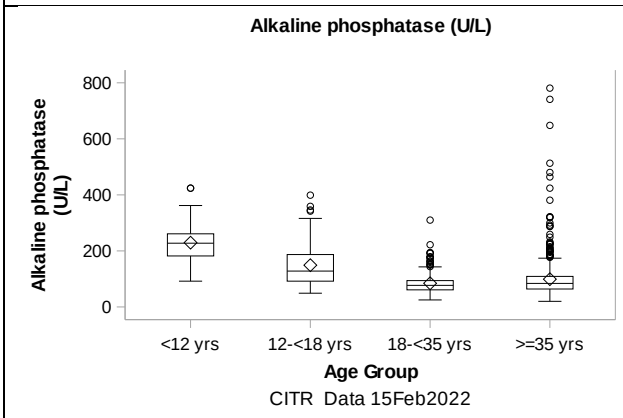


Exhibit 2 – 5 (continued)
Recipient Laboratory Values at First Infusion





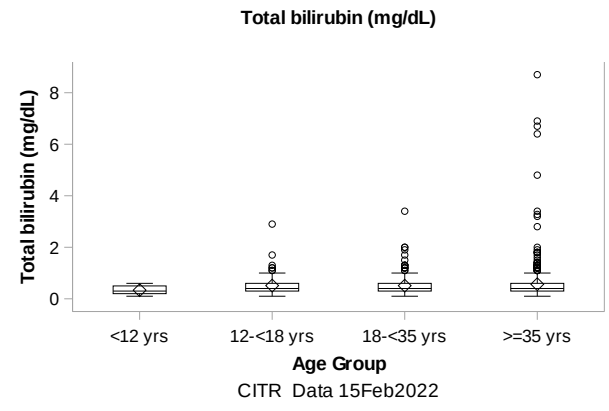


Exhibit 2 – 5 (continued)
Recipient Laboratory Values at First Infusion

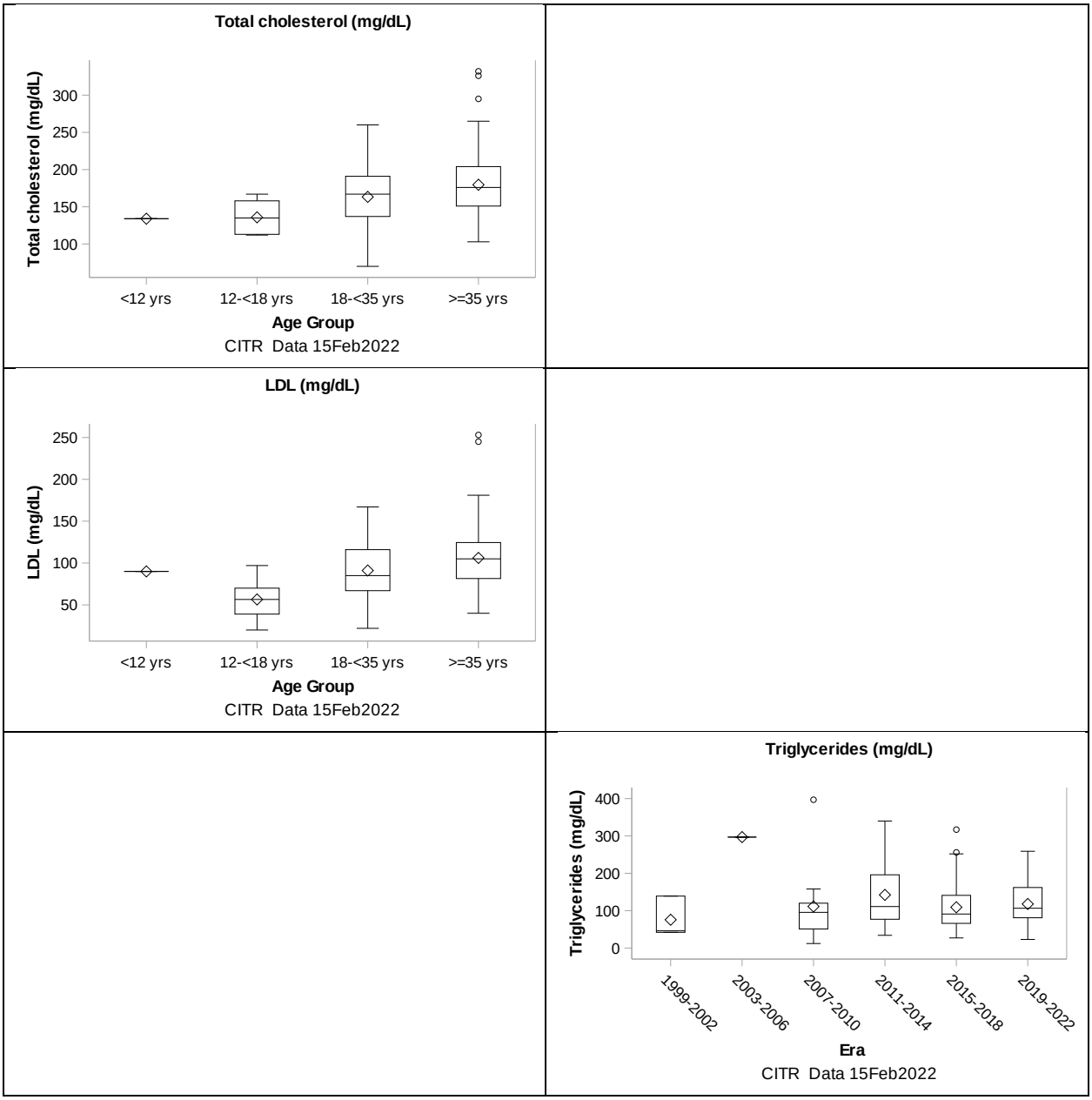
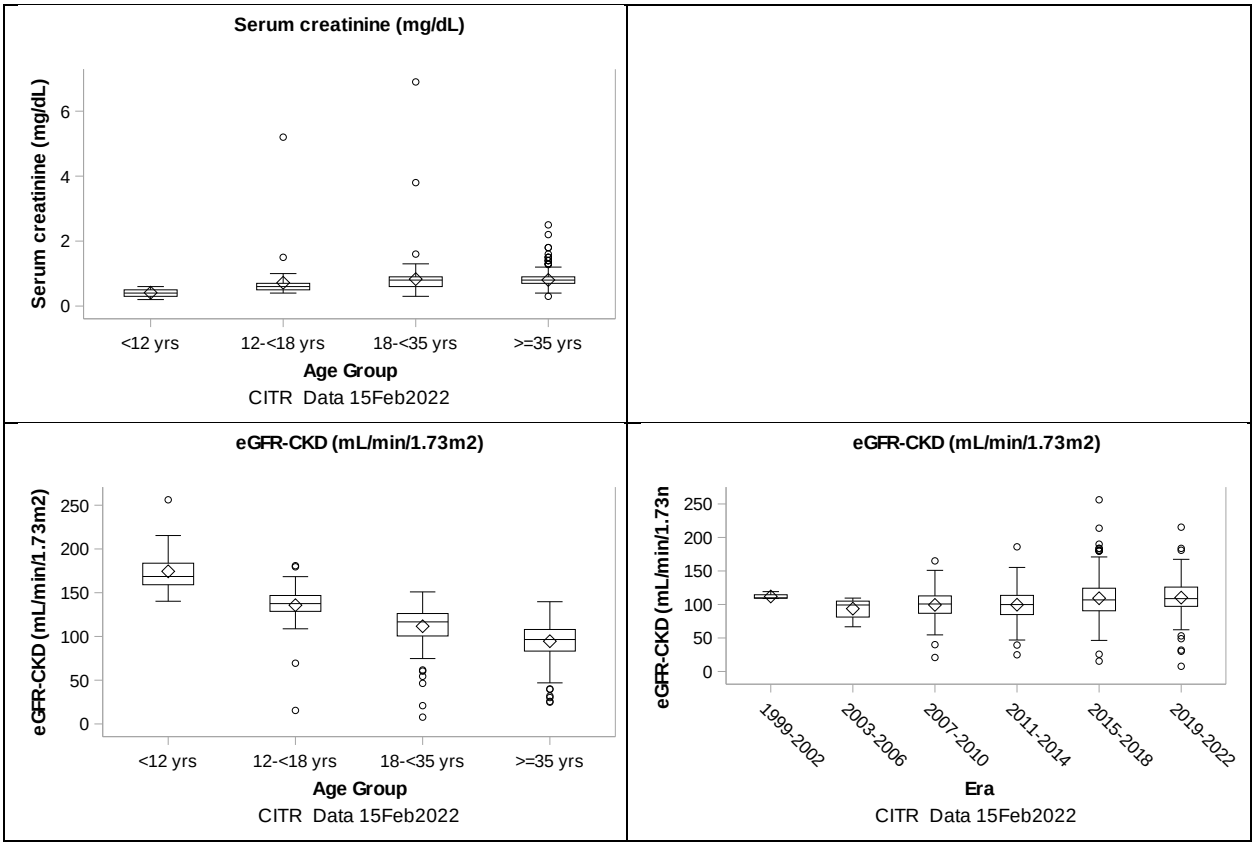


Exhibit 2 – 5 (continued)
Recipient Laboratory Values at First Infusion



Chapter 3

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 0.6±0.1 (1999-2002) to 2.3±2.1 (2007-2010) hours over the 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).

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

Exhibit 3 – 1A
Islet Processing Summary

		>=35 yrs		18-<35 yrs		12-<18 yrs		<12 yrs		p
		N	%	N	%	N	%	N	%	
Gradient type	**None**	225	66.0	101	78.3	49	96.1	29	96.7	
	Continuous	103	30.2	22	17.1	2	3.9	0	0.0	***
	Discontinuous	13	3.8	6	4.7	0	0.0	1	3.3	

Data completeness		>=35 yrs		18-<35 yrs		12-<18 yrs		<12 yrs		
		N	%	N	%	N	%	N	%	
Gradient type	Available	341	45.0	129	39.6	51	42.5	30	44.1	
	Missing	416	55.0	197	60.4	69	57.5	38	55.9	

		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		p
		N	%	N	%	N	%	N	%	N	%	N	%	
Gradient type	**Continuous**	0	0.0	2	5.3	13	15.9	65	50.4	30	13.9	17	20.7	
	Discontinuous	0	0.0	2	5.3	8	9.8	7	5.4	0	0.0	3	3.7	***
	None	4	100.0	34	89.5	61	74.4	57	44.2	186	86.1	62	75.6	

Data completeness		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
Gradient type	Available	4	9.3	38	36.5	82	28.8	129	32.2	216	66.5	82	72.6	
	Missing	39	90.7	66	63.5	203	71.2	272	67.8	109	33.5	31	27.4	

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

Exhibit 3 – 1A
Islet Processing Summary (Continued)

		>=35 yrs		18-<35 yrs		<12 yrs		12-<18 yrs		p
		N	%	N	%	N	%	N	%	
Incubated in preservation solution	**No**	268	84.3	79	86.8	9	100.0	24	96.0	
	Yes	50	15.7	12	13.2	0	0.0	1	4.0	

Data completeness		>=35 yrs		18-<35 yrs		12-<18 yrs		<12 yrs		
		N	%	N	%	N	%	N	%	
Incubated in preservation solution	Available	318	42.0	91	27.9	25	20.8	9	13.2	
	Missing	439	58.0	235	72.1	95	79.2	59	86.8	

		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		p
		N	%	N	%	N	%	N	%	N	%	N	%	
Incubated in preservation solution	**No**	4	100.0	11	91.7	64	80.0	134	84.3	133	92.4	34	77.3	*
	Yes	0	0.0	1	8.3	16	20.0	25	15.7	11	7.6	10	22.7	

Data completeness		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
Incubated in preservation solution	Available	4	9.3	12	11.5	80	28.1	159	39.7	144	44.3	44	38.9	
	Missing	39	90.7	92	88.5	205	71.9	242	60.3	181	55.7	69	61.1	

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

Exhibit 3 – 1A
Islet Processing Summary (Continued)

		>=35 yrs		18-<35 yrs		<12 yrs		12-<18 yrs		p
		N	%	N	%	N	%	N	%	
Preservation solution used	**Yes**	297	97.1	83	97.6	9	100.0	25	96.2	
	No	9	2.9	2	2.4	0	0.0	1	3.8	

Data completeness		>=35 yrs		18-<35 yrs		12-<18 yrs		<12 yrs		
		N	%	N	%	N	%	N	%	
Preservation solution used	Available	306	40.4	85	26.1	26	21.7	9	13.2	
	Missing	451	59.6	241	73.9	94	78.3	59	86.8	

		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		p
		N	%	N	%	N	%	N	%	N	%	N	%	
Preservation solution used	**No**	1	33.3	0	0.0	3	4.1	5	3.1	0	0.0	3	7.3	**
	Yes	2	66.7	9	100.0	71	95.9	156	96.9	138	100.0	38	92.7	

Data completeness		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
Preservation solution used	Available	3	7.0	9	8.7	74	26.0	161	40.1	138	42.5	41	36.3	
	Missing	40	93.0	95	91.3	211	74.0	240	59.9	187	57.5	72	63.7	

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

Exhibit 3 – 1A
Islet Processing Summary (Continued)

		>=35 yrs		18-<35 yrs		12-<18 yrs		<12 yrs		p
		N	%	N	%	N	%	N	%	
Islet purification	**None**	225	60.5	101	69.7	49	87.5	29	93.5	***
	Density gradient	135	36.3	37	25.5	4	7.1	2	6.5	
	Other	12	3.2	7	4.8	3	5.4	0	0.0	

Data completeness		>=35 yrs		18-<35 yrs		12-<18 yrs		<12 yrs		
		N	%	N	%	N	%	N	%	
Islet purification	Available	372	49.1	145	44.5	56	46.7	31	45.6	
	Missing	385	50.9	181	55.5	64	53.3	37	54.4	

		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		p
		N	%	N	%	N	%	N	%	N	%	N	%	
Islet purification	**Density gradient**	0	0.0	4	9.5	22	23.9	73	56.2	59	24.1	20	22.0	***
	None	4	100.0	34	81.0	61	66.3	57	43.8	186	75.9	62	68.1	
	Other	0	0.0	4	9.5	9	9.8	0	0.0	0	0.0	9	9.9	

Data completeness		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022		
		N	%	N	%	N	%	N	%	N	%	N	%	
Islet purification	Available	4	9.3	42	40.4	92	32.3	130	32.4	245	75.4	91	80.5	
	Missing	39	90.7	62	59.6	193	67.7	271	67.6	80	24.6	22	19.5	

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

Exhibit 3 – 1B
Final Islet Preparation Microbiology

		>=35 yrs		18-<35 yrs		<12 yrs		12-<18 yrs	
		N	%	N	%	N	%	N	%
Gram stain	**Negative**	238	80.7	75	84.3	6	75.0	19	79.2
	Positive	57	19.3	14	15.7	2	25.0	5	20.8

Data completeness		>=35 yrs		18-<35 yrs		12-<18 yrs		<12 yrs	
		N	%	N	%	N	%	N	%
Gram stain	Available	295	39.0	89	27.3	24	20.0	8	11.8
	Missing	462	61.0	237	72.7	96	80.0	60	88.2

		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022	
		N	%	N	%	N	%	N	%	N	%	N	%
Gram stain	**Negative**	1	100.0	11	100.0	50	79.4	132	82.5	115	79.9	29	78.4
	Positive	-	0.0	-	0.0	13	20.6	28	17.5	29	20.1	8	21.6

Data completeness		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022	
		N	%	N	%	N	%	N	%	N	%	N	%
Gram stain	Available	1	2.3	11	10.6	63	22.1	160	39.9	144	44.3	37	32.7
	Missing	42	97.7	93	89.4	222	77.9	241	60.1	181	55.7	76	67.3

Exhibit 3 – 1B
Final Islet Preparation Microbiology (Continued)

		>=35 yrs		18-<35 yrs		12-<18 yrs		<12 yrs	
		N	%	N	%	N	%	N	%
Aerobic culture	**Negative**	236	82.2	81	77.1	18	69.2	5	55.6
	Positive	51	17.8	24	22.9	8	30.8	4	44.4

Data completeness		>=35 yrs		18-<35 yrs		12-<18 yrs		<12 yrs	
		N	%	N	%	N	%	N	%
Aerobic culture	Available	287	37.9	105	32.2	26	21.7	9	13.2
	Missing	470	62.1	221	67.8	94	78.3	59	86.8

		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022	
		N	%	N	%	N	%	N	%	N	%	N	%
Aerobic culture	**Negative**	1	100.0	24	66.7	94	86.2	104	79.4	89	76.7	28	82.4
	Positive	-	0.0	12	33.3	15	13.8	27	20.6	27	23.3	6	17.6

Data completeness		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022	
		N	%	N	%	N	%	N	%	N	%	N	%
Aerobic culture	Available	1	2.3	36	34.6	109	38.2	131	32.7	116	35.7	34	30.1
	Missing	42	97.7	68	65.4	176	61.8	270	67.3	209	64.3	79	69.9

Exhibit 3 – 1B
Final Islet Preparation Microbiology (Continued)

		>=35 yrs		18-<35 yrs		12-<18 yrs		<12 yrs	
		N	%	N	%	N	%	N	%
Anaerobic culture	**Negative**	248	85.2	79	76.0	20	76.9	4	44.4
	Positive	43	14.8	25	24.0	6	23.1	5	55.6

Data completeness		>=35 yrs		18-<35 yrs		12-<18 yrs		<12 yrs	
		N	%	N	%	N	%	N	%
Anaerobic culture	**Available**	291	38.4	104	31.9	26	21.7	9	13.2
	Missing	466	61.6	222	68.1	94	78.3	59	86.8

		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022	
		N	%	N	%	N	%	N	%	N	%	N	%
Anaerobic culture	**Negative**	1	100.0	32	94.1	103	89.6	102	78.5	93	80.9	20	57.1
	Positive	-	0.0	2	5.9	12	10.4	28	21.5	22	19.1	15	42.9

Data completeness		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022	
		N	%	N	%	N	%	N	%	N	%	N	%
Anaerobic culture	**Available**	1	2.3	34	32.7	115	40.4	130	32.4	115	35.4	35	31.0
	Missing	42	97.7	70	67.3	170	59.6	271	67.6	210	64.6	78	69.0

Exhibit 3 – 1B
Final Islet Preparation Microbiology (Continued)

		>=35 yrs		18-<35 yrs		<12 yrs		12-<18 yrs	
		N	%	N	%	N	%	N	%
Fungal Culture	**Negative**	233	98.3	78	96.3	9	100.0	20	100.0
	Positive	4	1.7	3	3.7	-	0.0	-	0.0

Data completeness		>=35 yrs		18-<35 yrs		12-<18 yrs		<12 yrs	
		N	%	N	%	N	%	N	%
Fungal Culture	Available	237	31.3	81	24.8	20	16.7	9	13.2
	Missing	520	68.7	245	75.2	100	83.3	59	86.8

		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022	
		N	%	N	%	N	%	N	%	N	%	N	%
Fungal Culture	**Negative**	1	100.0	11	100.0	53	98.1	127	96.9	114	98.3	34	100.0
	Positive	-	0.0	-	0.0	1	1.9	4	3.1	2	1.7	-	0.0

Data completeness		1999-2002		2003-2006		2007-2010		2011-2014		2015-2018		2019-2022	
		N	%	N	%	N	%	N	%	N	%	N	%
Fungal Culture	Available	1	2.3	11	10.6	54	18.9	131	32.7	116	35.7	34	30.1
	Missing	42	97.7	93	89.4	231	81.1	270	67.3	209	64.3	79	69.9

Exhibit 3 – 2
Cold ischemia information

	Age Group												p
	<12 yrs			12-<18 yrs			18-<35 yrs			>=35 yrs			
	N	Mean	SD	N	Mean	SD	N	Mean	SD	N	Mean	SD	
Time from admission to pancreatectomy (hrs)	3	19.2	4.7	9	14.8	12.4	31	11.4	23.5	72	20.1	38.3	
Time from pancreatectomy to transplant (hrs)	1	6.3	-	7	4.9	2.2	29	4.6	5.8	83	7.6	11.5	
Time from cross clamp to pancreas recovery (hrs)	0	-	-	0	-	-	0	-	-	0	-	-	
Duration of cold ischemia (hrs)	9	1.1	1.3	18	2.4	2.1	62	1.5	1.8	214	1.6	1.7	
Culture time (hrs)	0	-	-	0	-	-	0	-	-	0	-	-	

	Era																		p
	1999-2002			2003-2006			2007-2010			2011-2014			2015-2018			2019-2022			
	N	Mean	SD	N	Mean	SD	N	Mean	SD	N	Mean	SD	N	Mean	SD	N	Mean	SD	
Time from admission to pancreatectomy (hrs)	4	51.3	19.7	5	40.2	30.0	8	30.6	35.5	35	6.7	6.8	35	11.1	17.2	28	25.6	55.3	
Time from pancreatectomy to transplant (hrs)	0	-	-	8	1.0	0.7	13	4.9	7.8	38	3.9	2.7	34	3.9	2.3	27	16.6	16.8	***
Time from cross clamp to pancreas recovery (hrs)	0	-	-	0	-	-	0	-	-	0	-	-	0	-	-	0	-	-	
Duration of cold ischemia (hrs)	4	0.6	0.1	9	1.4	0.5	35	2.3	2.1	123	1.7	1.9	103	1.4	1.5	29	1.6	1.4	
Culture time (hrs)	0	-	-	0	-	-	0	-	-	0	-	-	0	-	-	0	-	-	

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

Infusions	Age Group												
	<12 yrs			12-<18 yrs			18-<35 yrs			>=35 yrs			
	N	Mean	SE	N	Mean	SE	N	Mean	SE	N	Mean	SE	p
Total cell volume	26	5.3	0.8	48	8.4	1.0	130	9.9	0.6	267	10.4	0.4	**
Total islet particles (final preparation)	64	209.4	13.4	110	274.1	15.2	289	301.9	10.9	609	273.5	6.9	
Embedded islets (%)	6	52.5	14.5	15	28.1	6.2	47	28.9	3.5	160	24.9	1.8	*
Islet equivalents (1000s)	65	175.1	11.7	112	250.7	15.0	293	275.3	10.7	614	266.5	7.6	*
Islet equivalents(1000s)/kg recipient	31	6.4	0.5	49	4.0	0.3	134	3.8	0.2	326	3.9	0.2	**
Total Endotoxin units	9	46.5	26.3	19	27.2	18.7	58	46.3	10.4	171	38.0	4.0	
Endotoxin units/kg recipient weight	9	0.9	0.4	17	0.5	0.4	56	0.6	0.1	160	0.5	0.1	
Islet viability	8	95.6	1.9	23	95.2	1.0	79	94.5	0.7	265	94.2	0.3	
Purity	8	20.6	4.6	15	23.2	3.5	51	25.2	2.8	153	28.8	1.9	

Infusions	Era																		
	1999-2002			2003-2006			2007-2010			2011-2014			2015-2018			2019-2022			
	N	Mean	SE	N	Mean	SE	N	Mean	SE	N	Mean	SE	N	Mean	SE	N	Mean	SE	p
Total cell volume	1	18.0	-	28	9.7	1.2	217	9.0	0.4	11	11.4	2.0	155	10.2	0.6	59	10.9	1.1	
Total islet particles (final preparation)	43	230.9	25.8	100	258.6	18.8	246	268.5	10.8	340	292.7	9.8	266	282.1	9.6	77	272.2	19.3	*
Embedded islets (%)	0	-	-	6	14.8	4.4	22	33.9	6.4	88	25.5	2.2	90	25.0	2.3	22	34.2	6.6	
Islet equivalents (1000s)	43	180.5	22.1	101	221.4	13.8	237	248.6	11.7	340	290.5	10.5	278	266.9	10.7	85	256.4	18.6	***
Islet equivalents(1000s)/kg recipient	4	3.6	1.6	10	3.0	0.4	56	3.7	0.5	139	4.3	0.2	249	4.0	0.2	82	4.0	0.3	
Total Endotoxin units	1	0.1	-	10	34.1	12.1	22	25.1	20.7	100	64.3	6.8	95	24.7	4.4	29	15.4	7.5	*
Endotoxin units/kg recipient weight	1	0.0	-	8	0.5	0.2	21	0.3	0.2	95	1.0	0.1	89	0.3	0.1	28	0.2	0.1	*
Islet viability	1	98.0	-	4	87.3	6.4	57	93.3	0.7	148	94.0	0.4	133	95.9	0.4	32	92.5	0.9	*
Purity	1	10.0	-	7	49.0	14.5	15	25.7	4.6	91	27.9	2.5	89	26.6	1.9	24	23.2	3.4	

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

Exhibit 3 – 4

Correlation of Islet Characteristics with Recipient, Recovery, and Processing Characteristics

Spearman Correlation Coefficients Prob > |r| under H0: Rho=0 Number of Observations	Packed cell volume	Total particle count	Trapped islets	Total IEQs infused	IEQs/kg donor	Total endotoxin	Endotoxin/kg donor
Age at Baseline (yrs)	0.10462 0.0229 473	-0.00011 0.9972 1075	-0.14462 0.0290 228	0.05338 0.0786 1087	-0.09433 0.0282 541	0.04636 0.4593 257	0.00828 0.8980 242
Weight(kg)	0.31522 <.0001 276	0.14333 0.0010 525	-0.01863 0.7864 214	0.23281 <.0001 534	-0.17686 <.0001 541	0.08014 0.2142 242	-0.05825 0.3669 242
Donor height	0.15367 0.0110 273	0.02151 0.6270 513	-0.03626 0.6005 211	0.07052 0.1052 529	-0.18806 <.0001 525	0.04478 0.4927 237	-0.02525 0.7026 231
Donor Body Mass Index (kg/m2)	0.30346 <.0001 269	0.15955 0.0003 504	-0.06350 0.3645 206	0.24952 <.0001 520	-0.12746 0.0034 525	0.07728 0.2420 231	-0.04486 0.4974 231
Hours from admission to pancreatectomy	-0.13247 0.4215 39	-0.09587 0.3687 90	-0.04398 0.7343 62	-0.09176 0.3843 92	-0.08808 0.4064 91	-0.09480 0.4316 71	-0.12490 0.3139 67
Hours from pancreatectomy to transplant	-0.29882 0.0413 47	-0.14191 0.1701 95	0.36044 0.0034 64	-0.08996 0.3809 97	-0.04626 0.6562 95	-0.14896 0.2117 72	-0.08136 0.5096 68
Cold ischemic time (hrs)	-0.15440 0.2158 66	-0.18265 0.0029 264	0.01832 0.8009 192	-0.20644 0.0008 259	-0.20729 0.0010 248	-0.11609 0.0910 213	-0.06862 0.3307 203

Chapter 4
AUTOGRAFT RECIPIENT MEDICATIONS

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Chapter 5

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 (exhibit 5-1B/A, p<0.0001) and those with HbA1c <6.5% at baseline (Exhibit 5-1B/B, p=0.002). Female recipients showed also greatly improved rates of insulin independence (Exhibit 5-1B/C, p<0.0001).

Islet particles ≥500,000 (Exhibit 5-1B/E, p=0.009), IEQs infused ≥300,000 (Exhibit 5-1B/F, p=0.008), and IEQs/kg ≥3,000 (Exhibit 5-1B/G, p=0.005) were all associated with higher rates of insulin independence.

Chronic pancreatitis as the indication for auto-ITx reduced insulin independence rates (Exhibit 5-1B/J, p=0.0007).

Absence of a prior ERCP improved insulin independence rates (Exhibit 5-1B/L, p=0.0006).

Recipients 18-35 years old

Islet particles ≥500,000 (Exhibit 5-1C/A, p=0.002), IEQs infused ≥275,000 (Exhibit 5-1C/B, p=0.001), and IEQs/kg ≥3,000 (Exhibit 5-1C/C, p=0.0005) were all associated with higher rates of insulin independence in this age group.

Recipients <18 years old

These groups had too small sample size to uncover any factors associated with improved levels of insulin independence following transplantation (Exhibits 5-1D) and (Exhibit 5-1E).

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 at baseline, being female, ≥300K IEQs infused, and IEQs/kg ≥3,000 were all associated with improved retention of C-peptide≥0.3ng/mL over 5 years. Observed differences across eras are not clearly explainable. In the 18-35 year-olds, higher number of islet particles at count, and IEQs infused improved rates of C-peptide≥0.3ng/mL (Exhibit 5-2C). There were no detectable factors for C-peptide≥0.3 ng/mL in the younger age groups.

Almost all patients had **fasting blood glucose (FBG) of 60-140 mg/dL** at baseline. Prevalence rates declined over five years post-transplant, but less so in younger age groups, with those <18 years old maintaining >80%, compared to 78% for 18-35 year-olds and 70% for those 35 and over (Exhibit 5-3A, p=0.002)

In the ≥35 age group, women (Exhibit 5-3B/A, p<0.0001) and those who received ≥300K IEQs, showed remarkably higher rates of FBG 460-140 (Exhibit 5-3B/B, p=0.0007).

No specific factors were associated with FBG 60-140 in auto-ITx recipients in age groups 18-<35, 12-<18, and <12 (Exhibit 5-3C, 5-3D, 5-3E).

Most auto-ITx patients had **HbA1c<7.0%** at baseline. These rates declined to between 50% and 70% with children <12-year-olds and adults ≥35 experiencing the greatest decline (Exhibit 5-4A, p=0.002).

In the ≥35 age group, women 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, women and those who received ≥275K IEQs, and those who received ≥3,000 IEQs/kg showed higher rates of HbA1c<7.0% (Exhibit 5-4C).

There were no specific factors influencing HbA1c<7.0% in the other age groups (Exhibit 5-4D and 5-4E).

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 5-5).

Insulin dose (Exh 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 IEQs infused with more IEQs associated with higher levels of fasting C-peptide.

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

Fasting blood glucose as a continuous variable (Exhibit 5-9) varied by 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. From available data, **Insulin Dose** (Exh 5-6) when reported did not vary by age, era, total IEQs infused, or pancreatitis etiology. **Fasting C-peptide** boxplots (Exhibit 5-7) decreased over time after TPIAT and differed by IEQs (higher IEQs were better) and pancreatitis etiology. **HbA1c boxplots** (Exhibit 5-8) varied by age group and pancreatitis etiology. **Fasting blood glucose** as a continuous variable (Exhibit 5-9) varied substantially by age and by pancreatitis etiology.

Exhibit 5 – 1A

Prevalence of Insulin Independence Post Last Infusion by Age Group (p<0.0001)

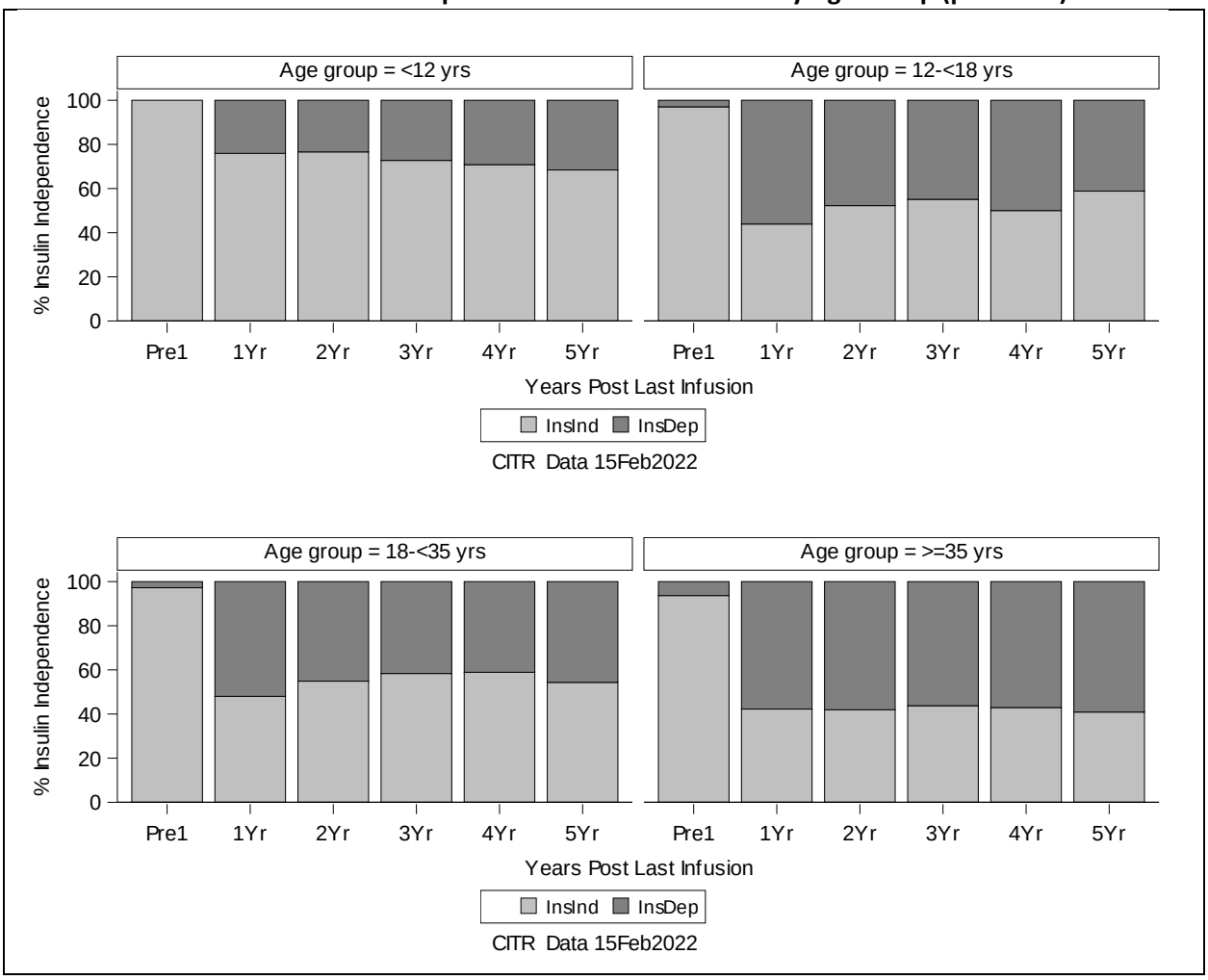
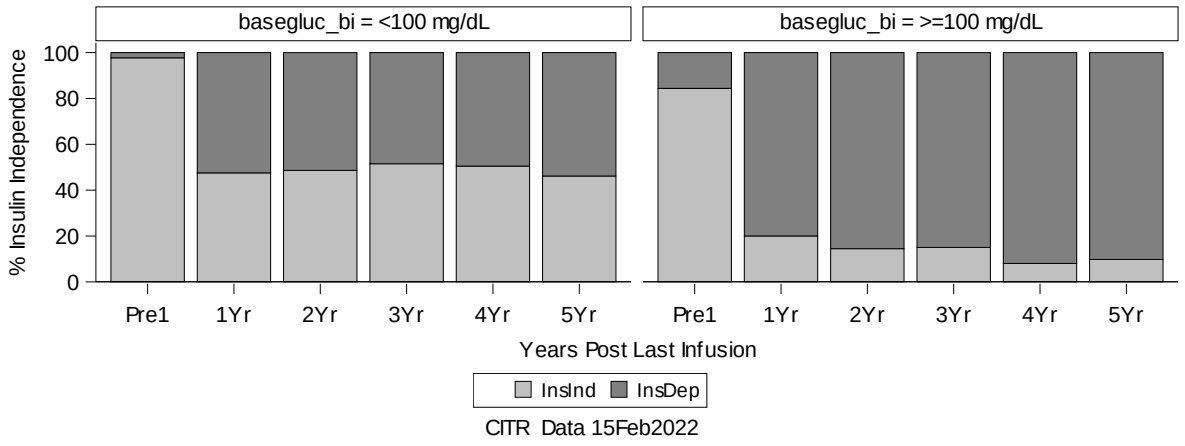
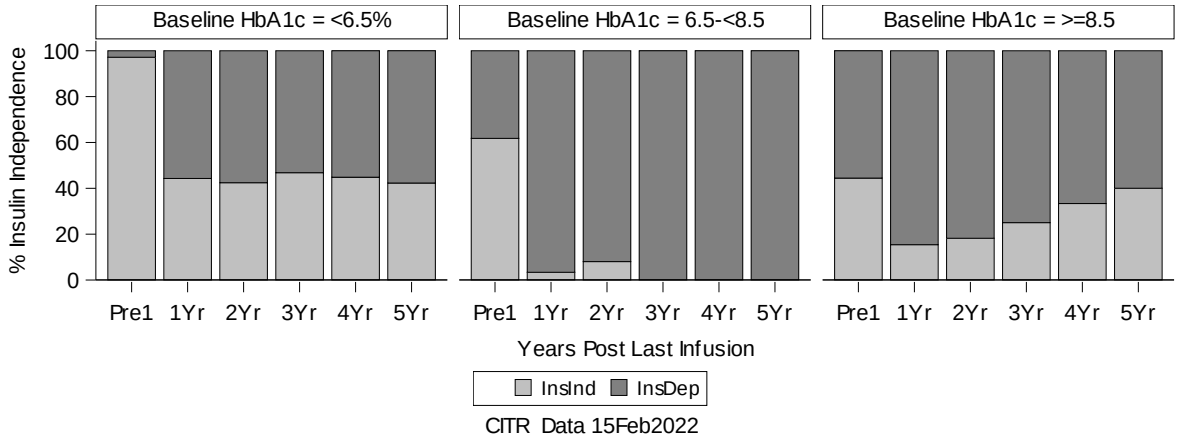


Exhibit 5 – 1B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Insulin Independence Post Last Infusion among Recipients 35 and over

A. Baseline Fasting Blood Glucose (p<0.0001)



B. Baseline HbA1c (p=0.002)



C. Sex (p<0.0001)

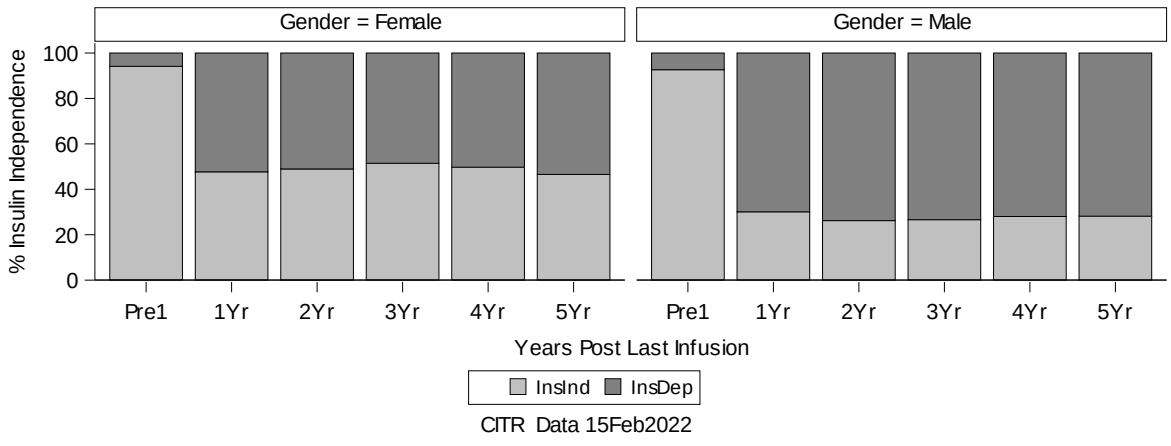
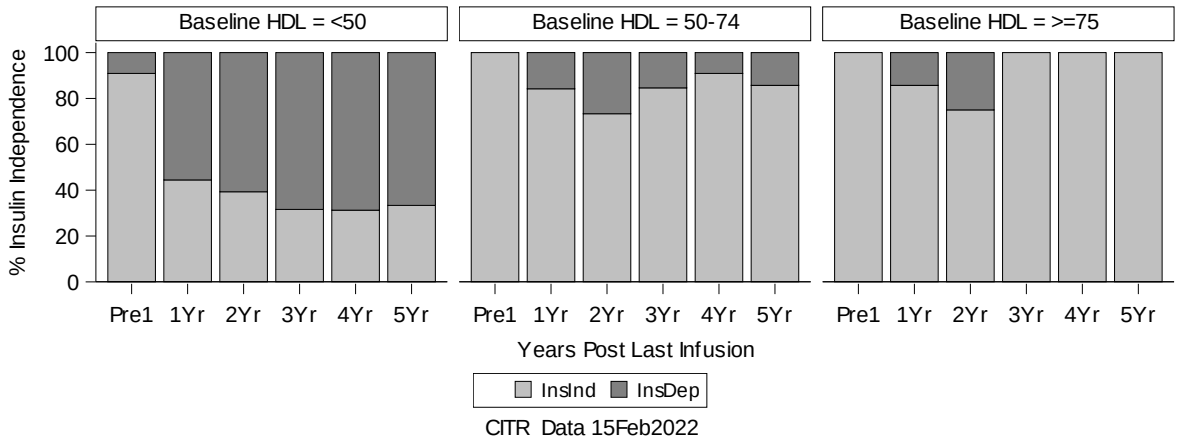
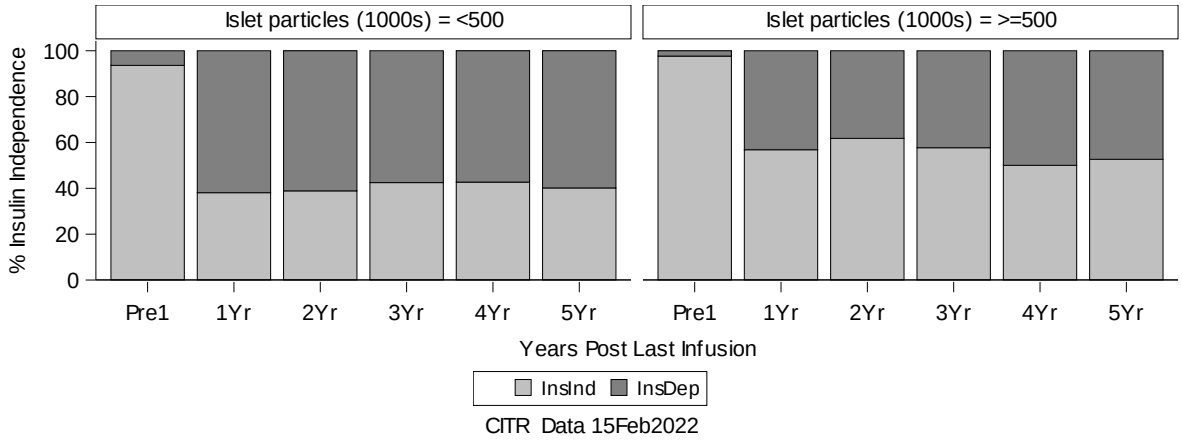


Exhibit 5 – 1B (continued)
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Insulin Independence Post Last Infusion among Recipients 35 and over

D. Baseline HDL (p=0.002)



E. Islet particles (1000s) (p=0.009)



F. IEQs infused (1000s) (p=0.008)

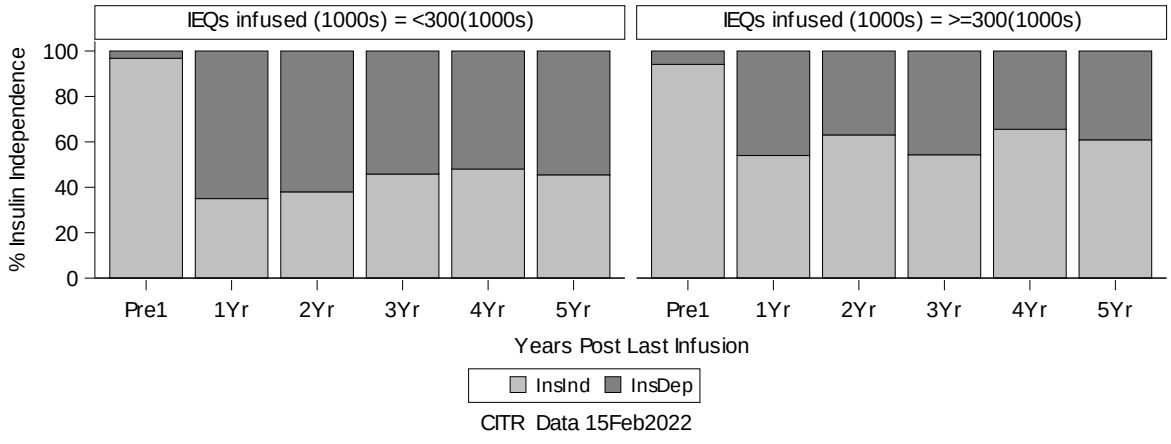
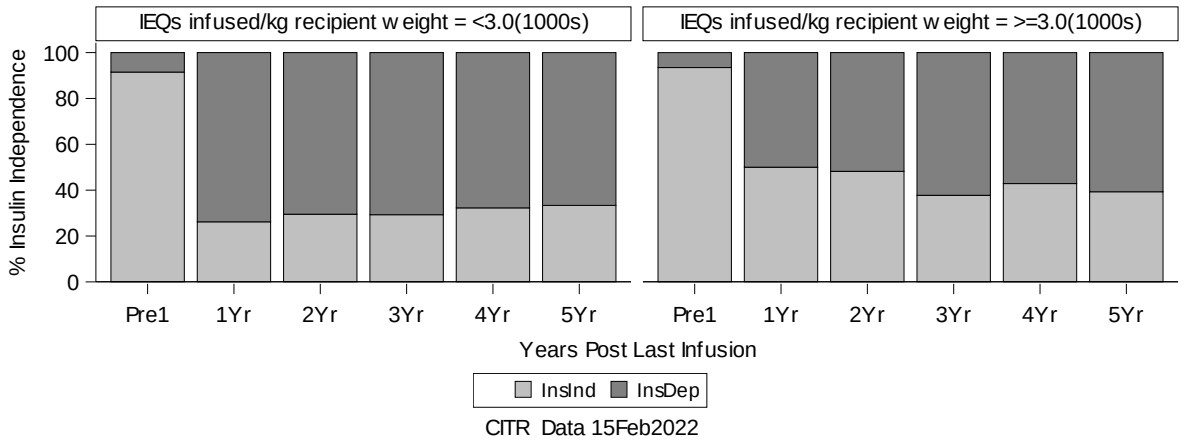
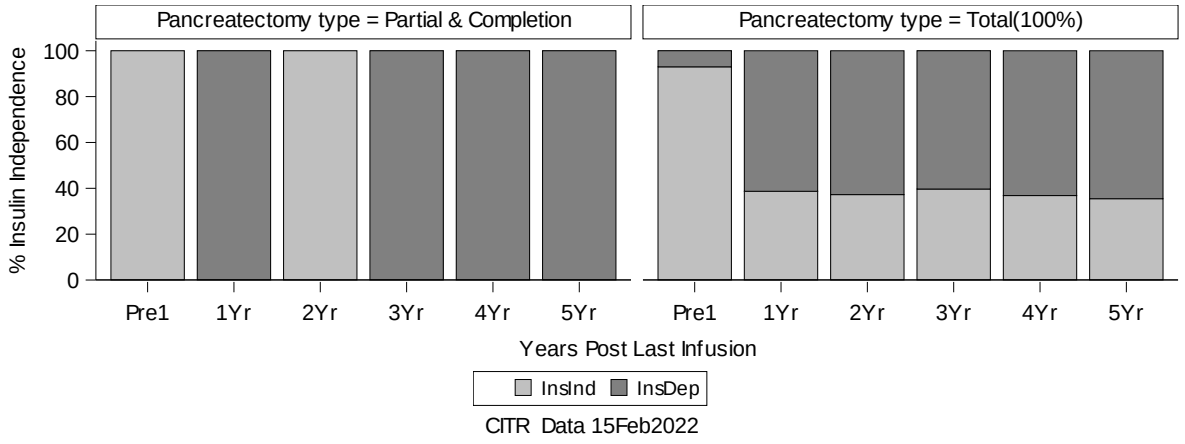


Exhibit 5 – 1B (continued)
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Insulin Independence Post Last Infusion among Recipients 35 and over

G. IEQs infused/kg recipient weight(p=0.005)



H. Pancreatectomy type (p<0.0001)



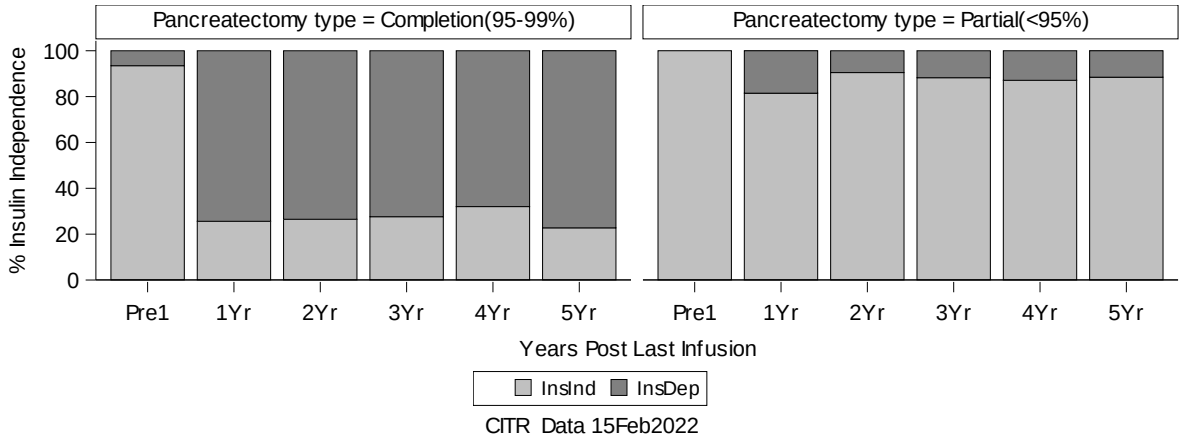
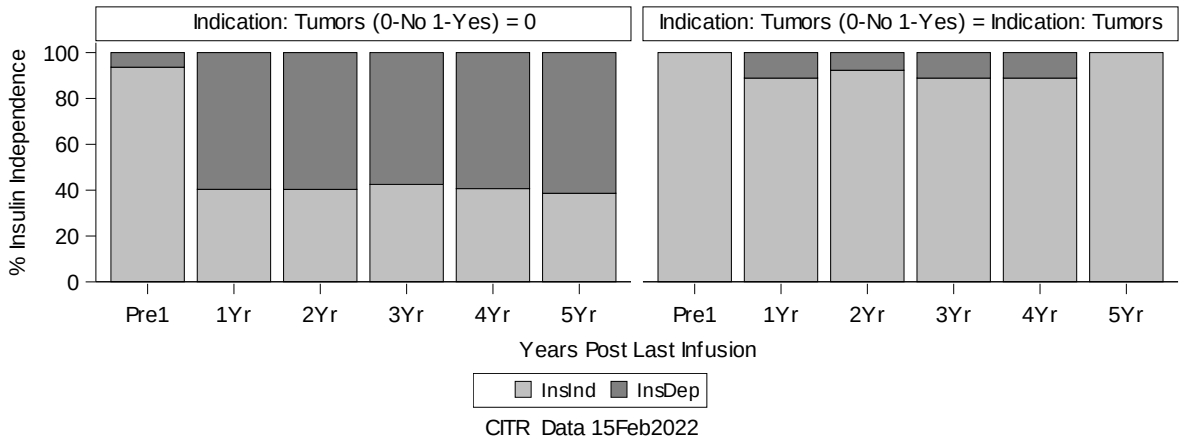
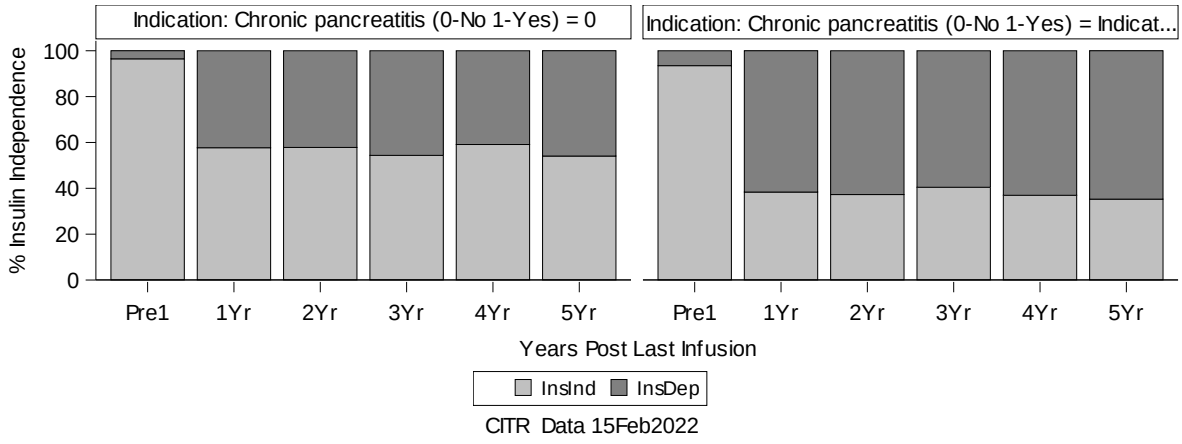


Exhibit 5 – 1B (continued)
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Insulin Independence Post Last Infusion among Recipients 35 and over

I. Indication: Tumors (p<0.0001)



J. Indication: Chronic pancreatitis (p=0.0007)



K. Incubated in preservation solution (p<0.0001)

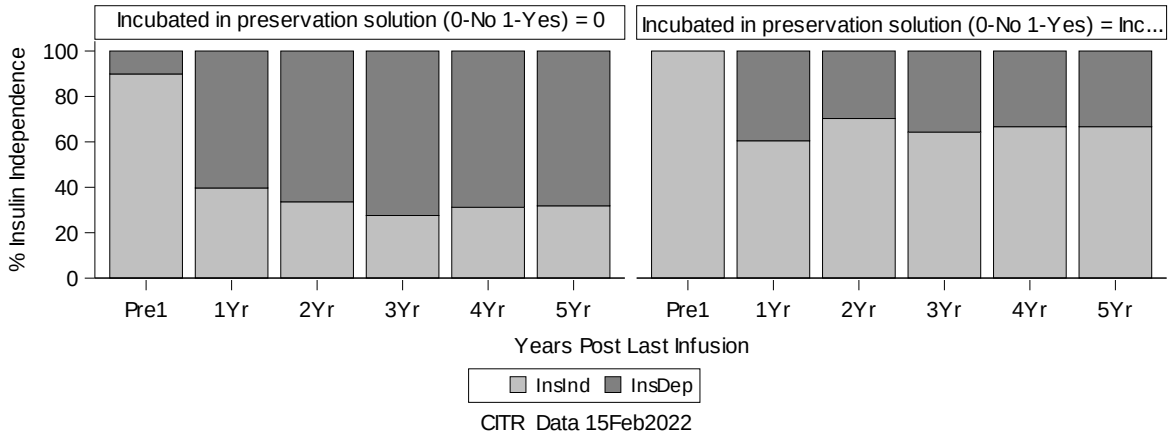


Exhibit 5 – 1B (continued)
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Insulin Independence Post Last Infusion among Recipients 35 and over

L. ERCP (p=0.0006)

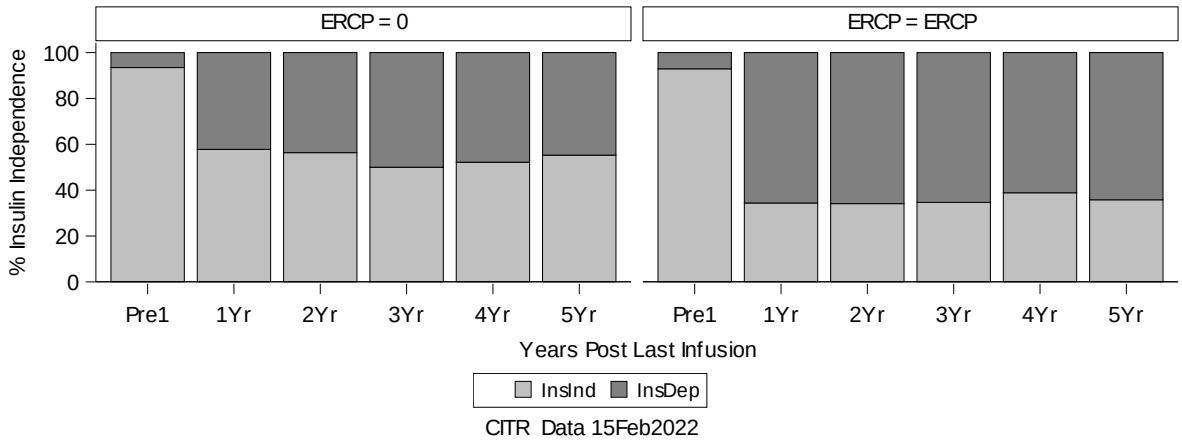
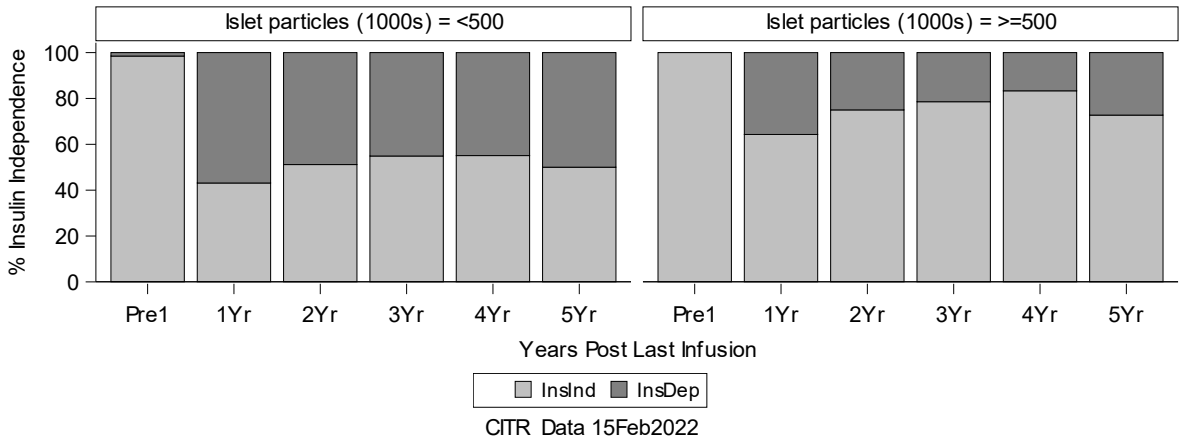
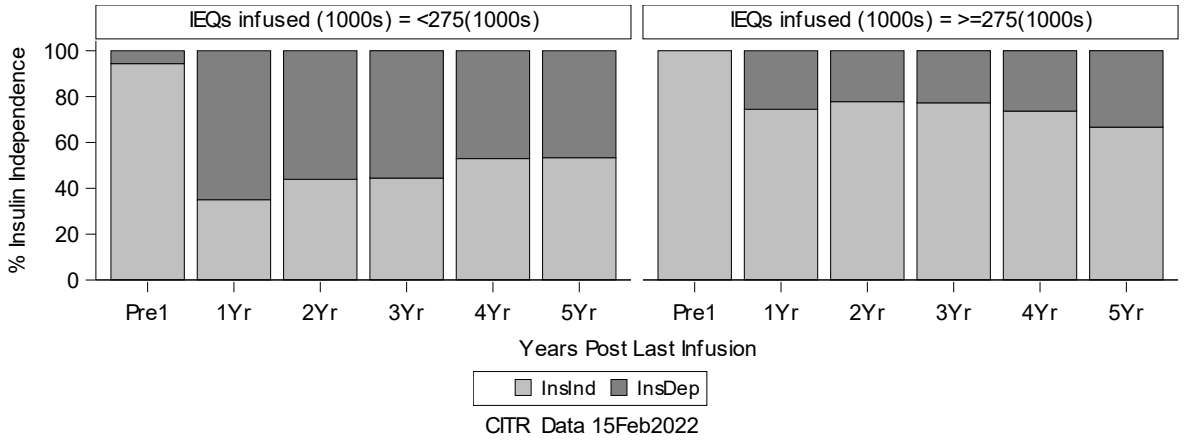


Exhibit 5 – 1C
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Insulin Independence Post Last Infusion among Recipients 18 to 35

A. Islet particles (1000s) (p=0.002)



B. IEQs infused (1000s) (p=0.001)



C. IEQs infused/kg recipient weight (p=0.0005)

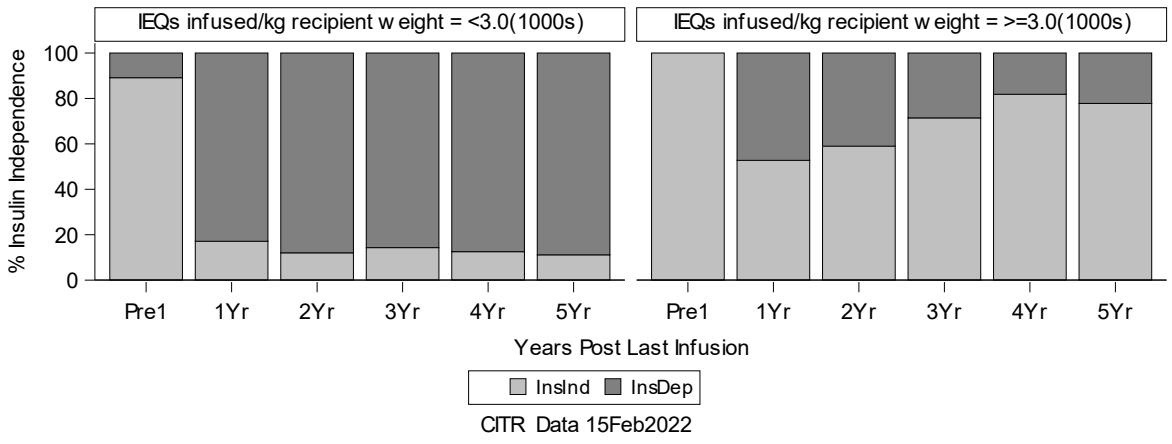
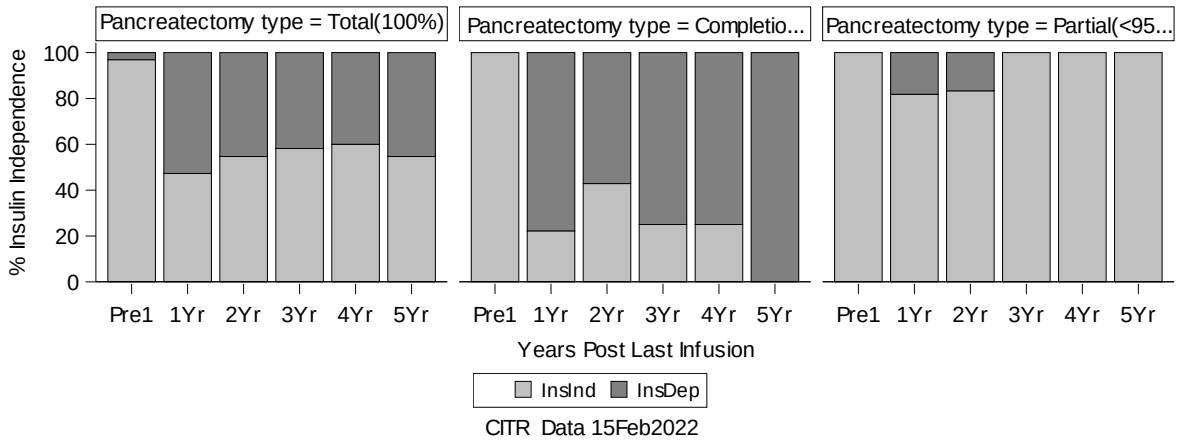


Exhibit 5 – 1C (continued)
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Insulin Independence Post Last Infusion among Recipients 18 to 35

D. Pancreatectomy type (p<0.0001)



E. Indication: Chronic pancreatitis (p=0.003)

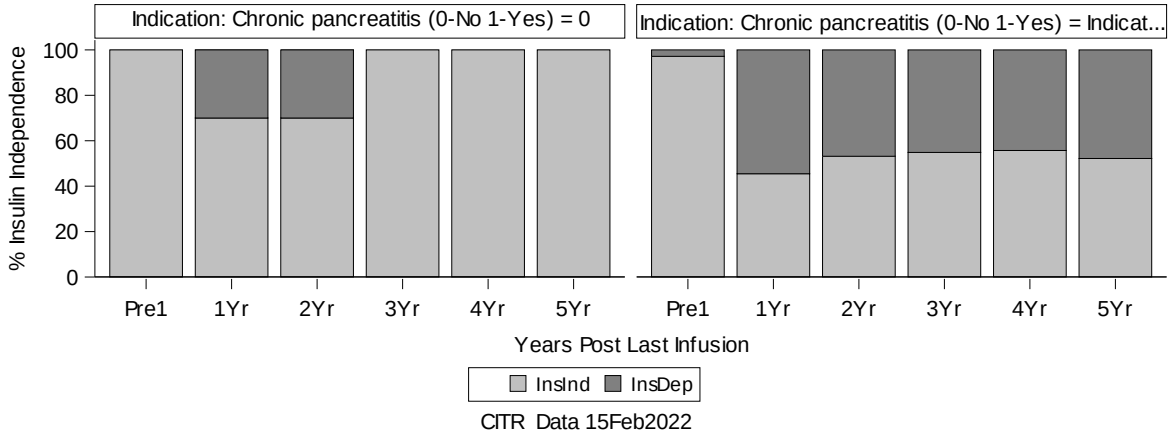


Exhibit 5 – 1D
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Insulin Independence Post Last Infusion among Recipients 12 to 18

None

Exhibit 5 – 1E
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Insulin Independence Post Last Infusion among Recipients 12 and under

None

Exhibit 5 – 2A

Prevalence of C-peptide ≥0.3 ng/mL Post Last Infusion by Age Group (p<0.0001)

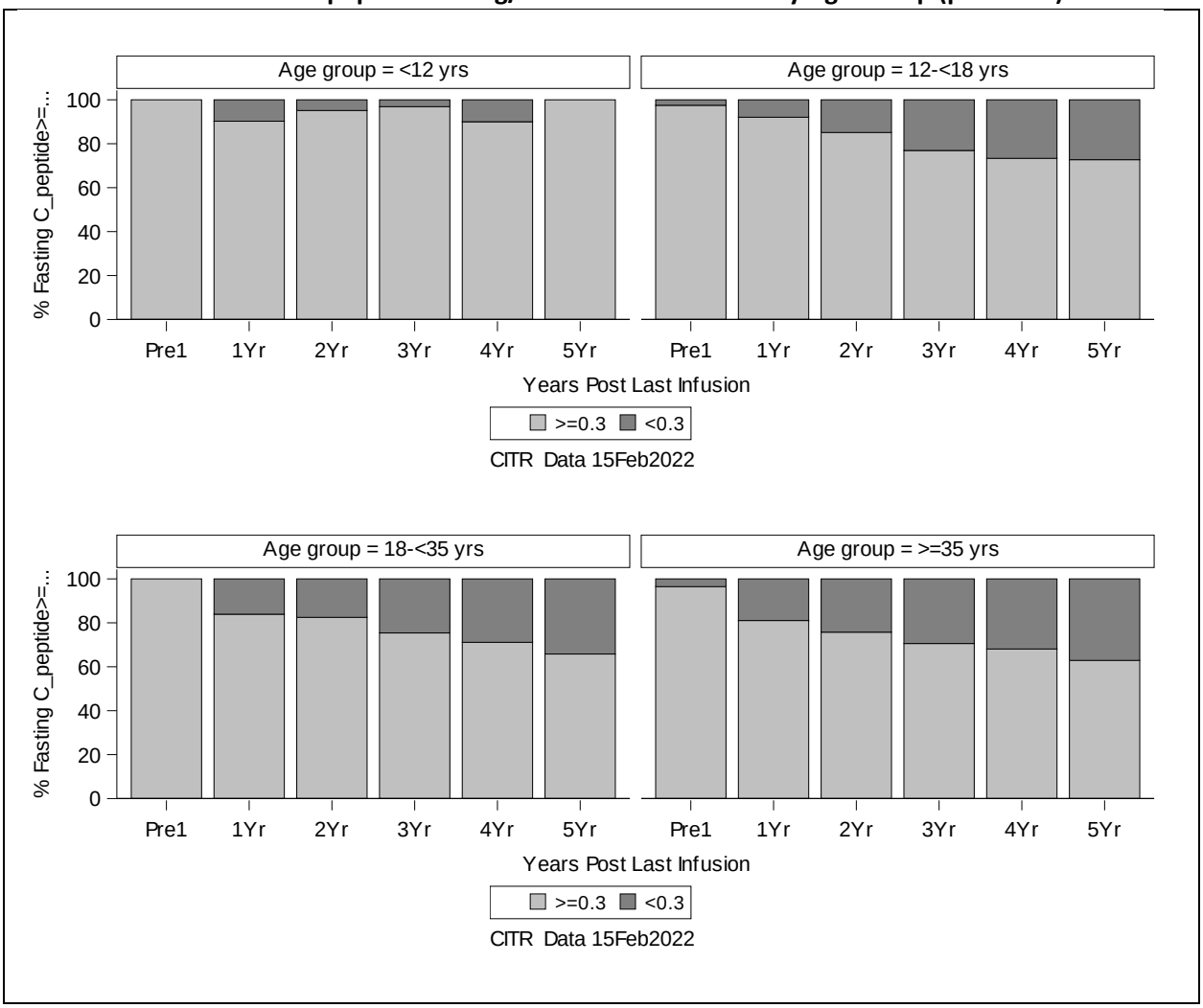
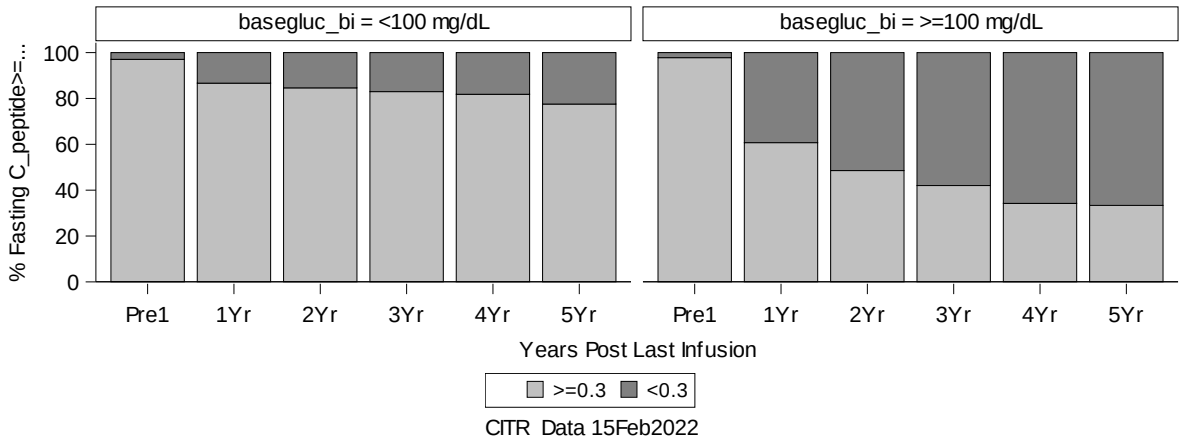
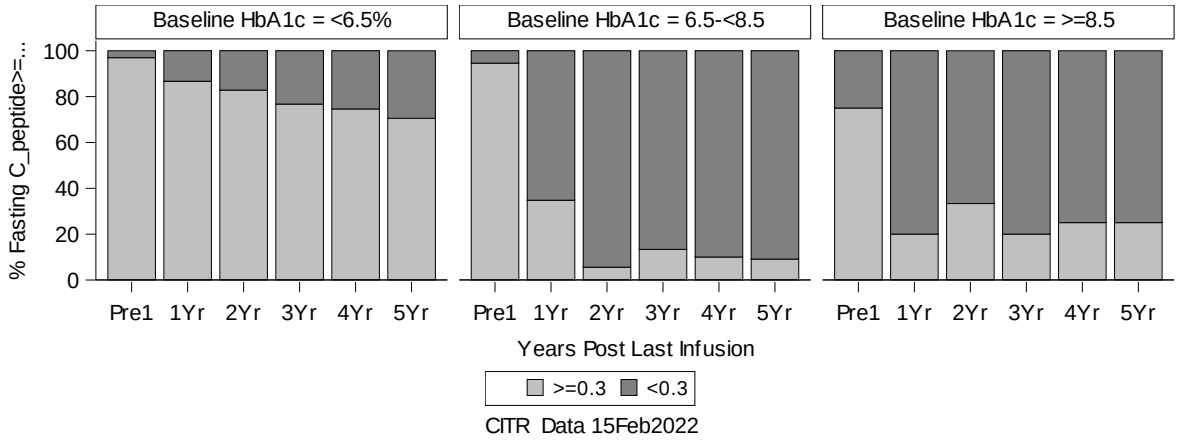


Exhibit 5 – 2B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of C-peptide ≥0.3 ng/mL Post Last Infusion among Recipients 35 and over

A. Baseline Fasting Blood Glucose (p<0.0001)



B. Baseline HbA1c (p<0.0001)



C. Sex (p=0.002)

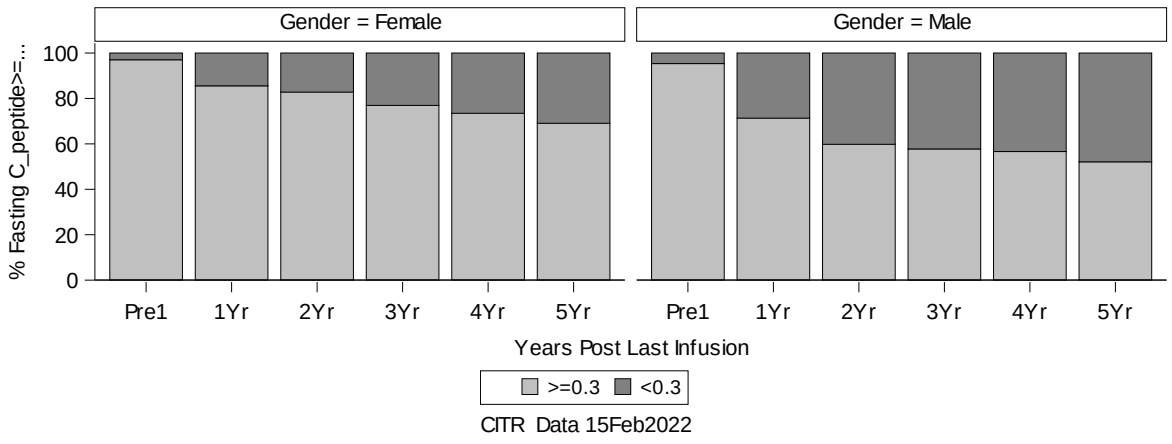
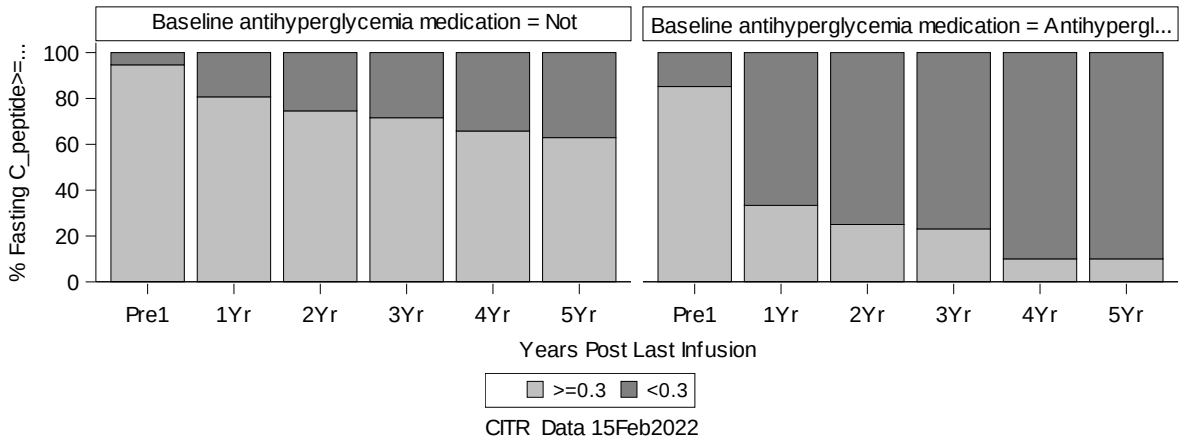
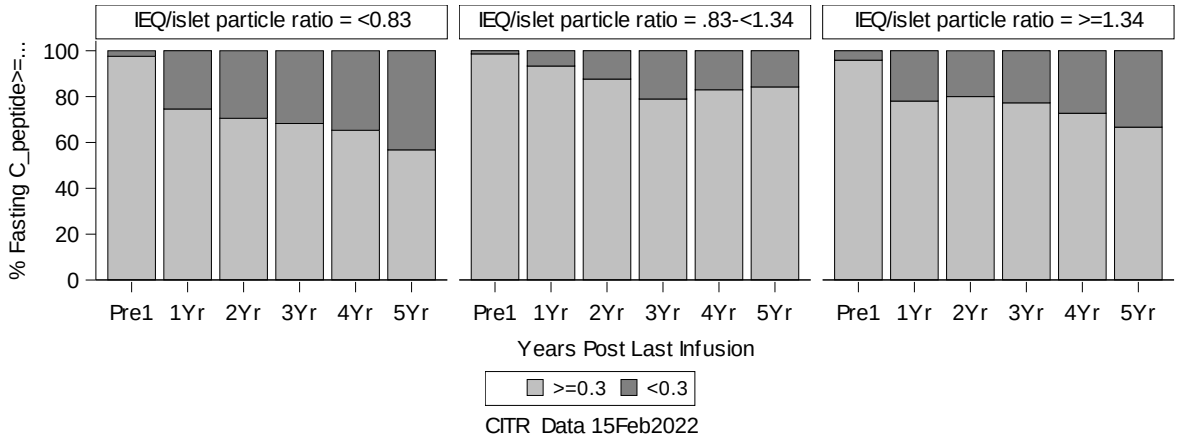


Exhibit 5 – 2B (continued)
Univariate Effects of Individual Variables (p<0.01) on Prevalence of C-peptide ≥0.3 ng/mL Post Last Infusion among Recipients 35 and over

D. Baseline antihyperglycemia medication (p=0.004)



E. IEQ/islet particle ratio (p=0.007)



F. IEQs infused (1000s) (p<0.0001)

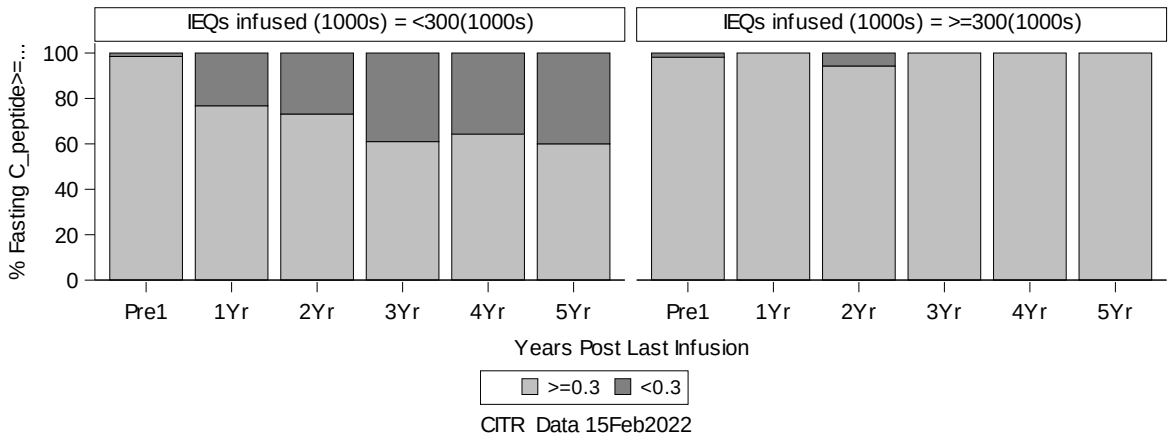
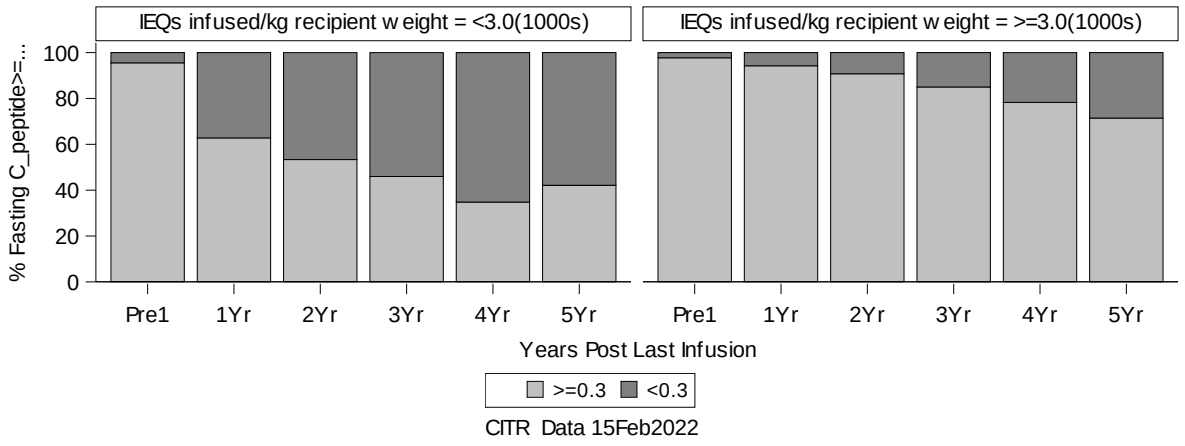
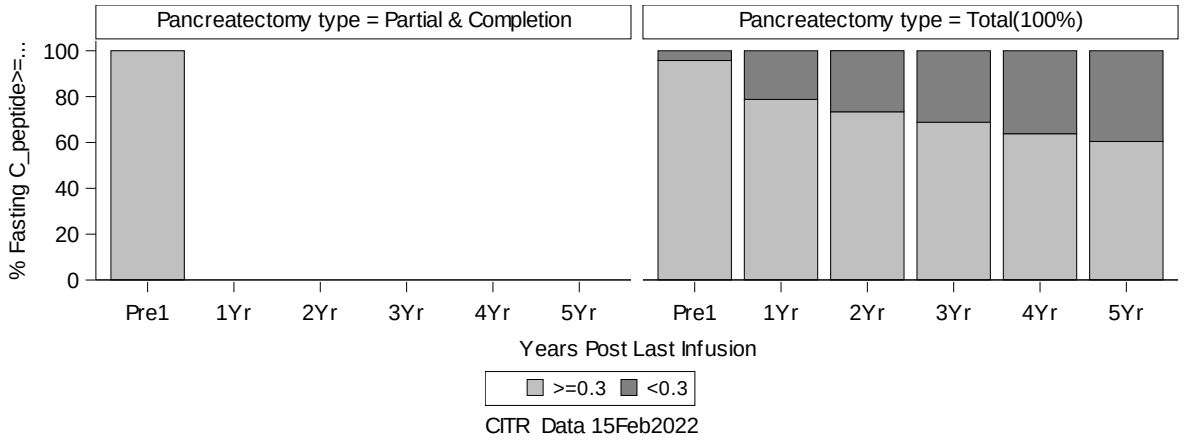


Exhibit 5 – 2B (continued)
Univariate Effects of Individual Variables (p<0.01) on Prevalence of C-peptide ≥0.3 ng/mL Post Last Infusion among Recipients 35 and over

G. IEQs infused/kg recipient weight (p<0.0001)



H. Pancreatectomy type (p<0.0001)



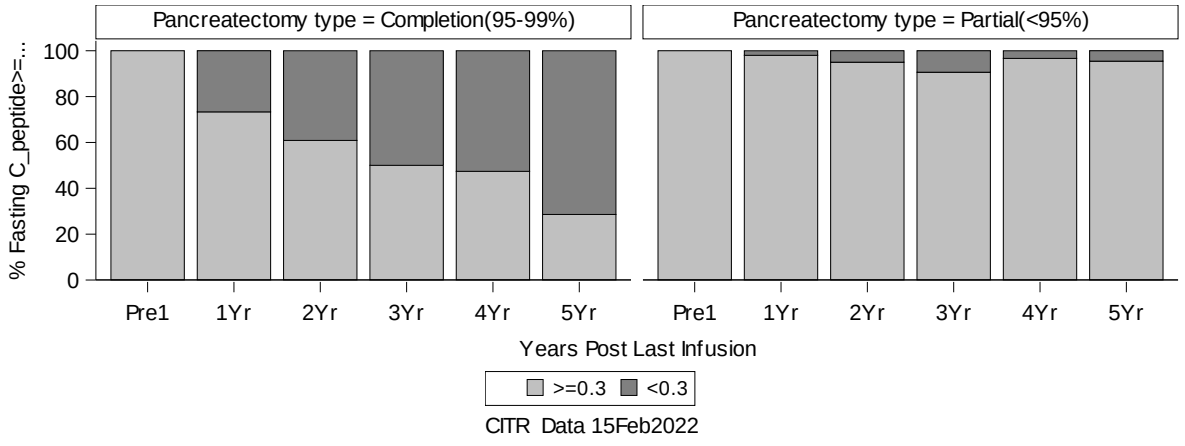
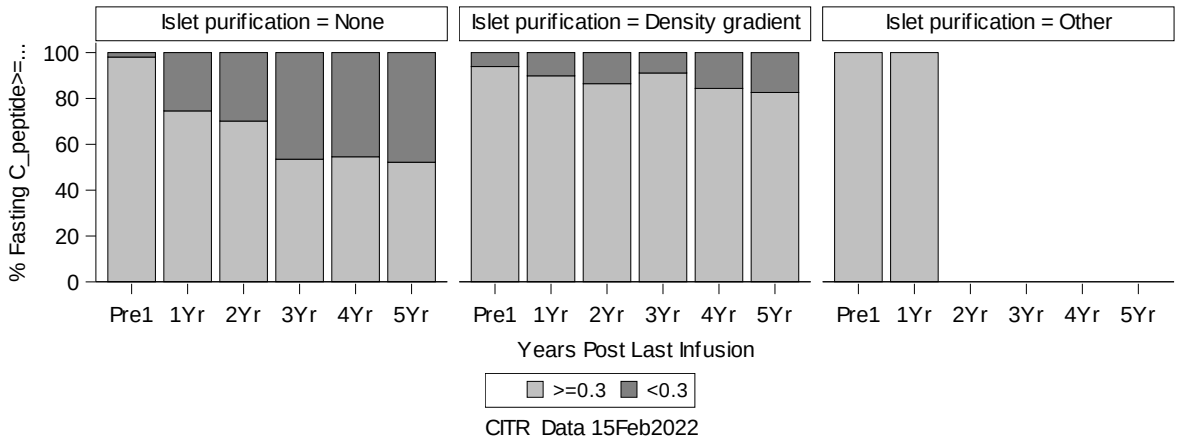
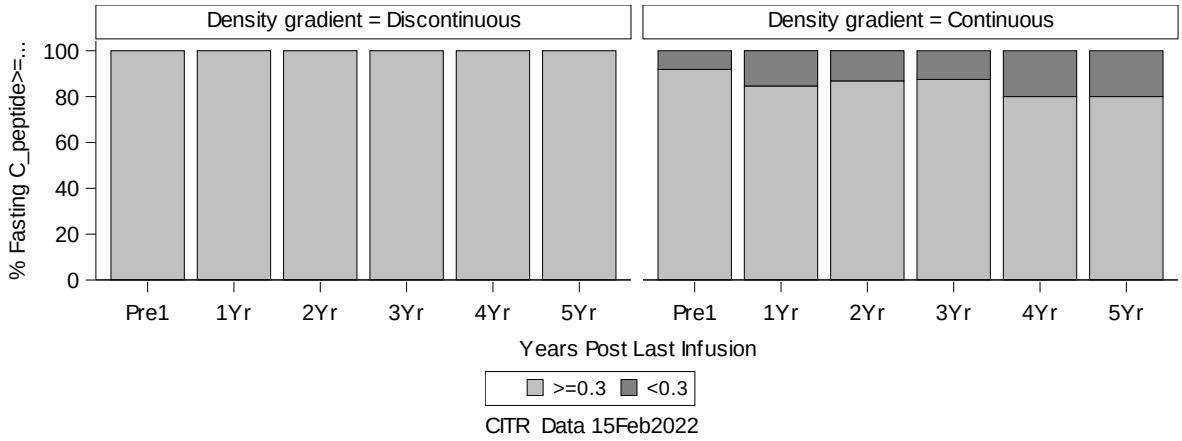


Exhibit 5 – 2B (continued)
Univariate Effects of Individual Variables (p<0.01) on Prevalence of C-peptide ≥0.3 ng/mL Post Last Infusion among Recipients 35 and over

I. Islet purification (p<0.0001)



J. Density gradient (p=0.005)



K. Indication: Tumors (p<0.0001)

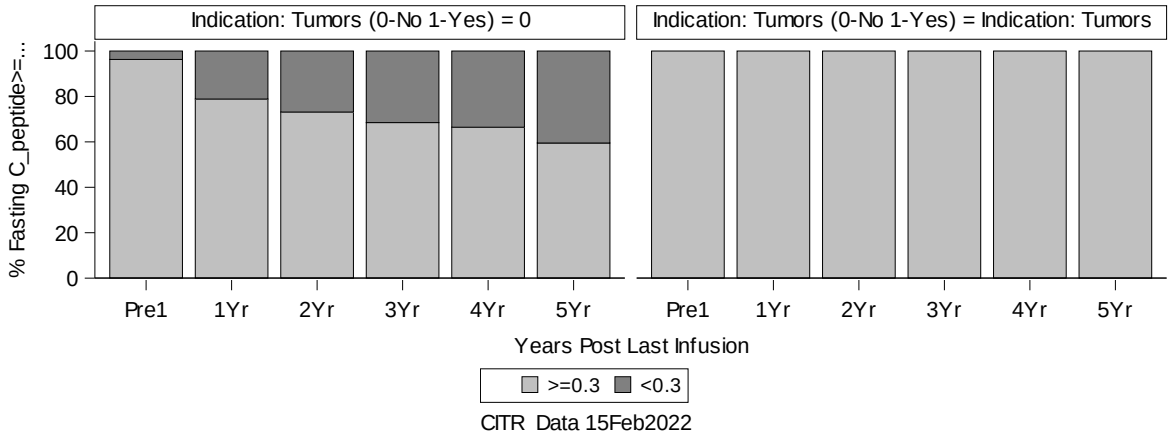


Exhibit 5 – 2B (continued)
Univariate Effects of Individual Variables (p<0.01) on Prevalence of C-peptide ≥0.3 ng/mL
Post Last Infusion among Recipients 35 and over

L. Incubated in preservation solution (p<0.0001)

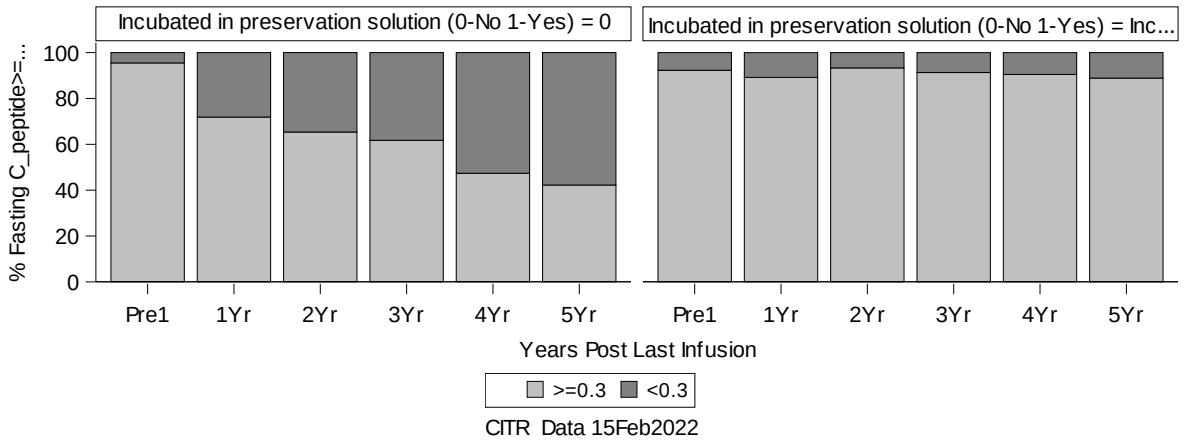


Exhibit 5 – 2B (continued)
Univariate Effects of Individual Variables (p<0.01) on Prevalence of C-peptide ≥0.3 ng/mL Post Last Infusion among Recipients 35 and over

M. Era (p<0.0001)

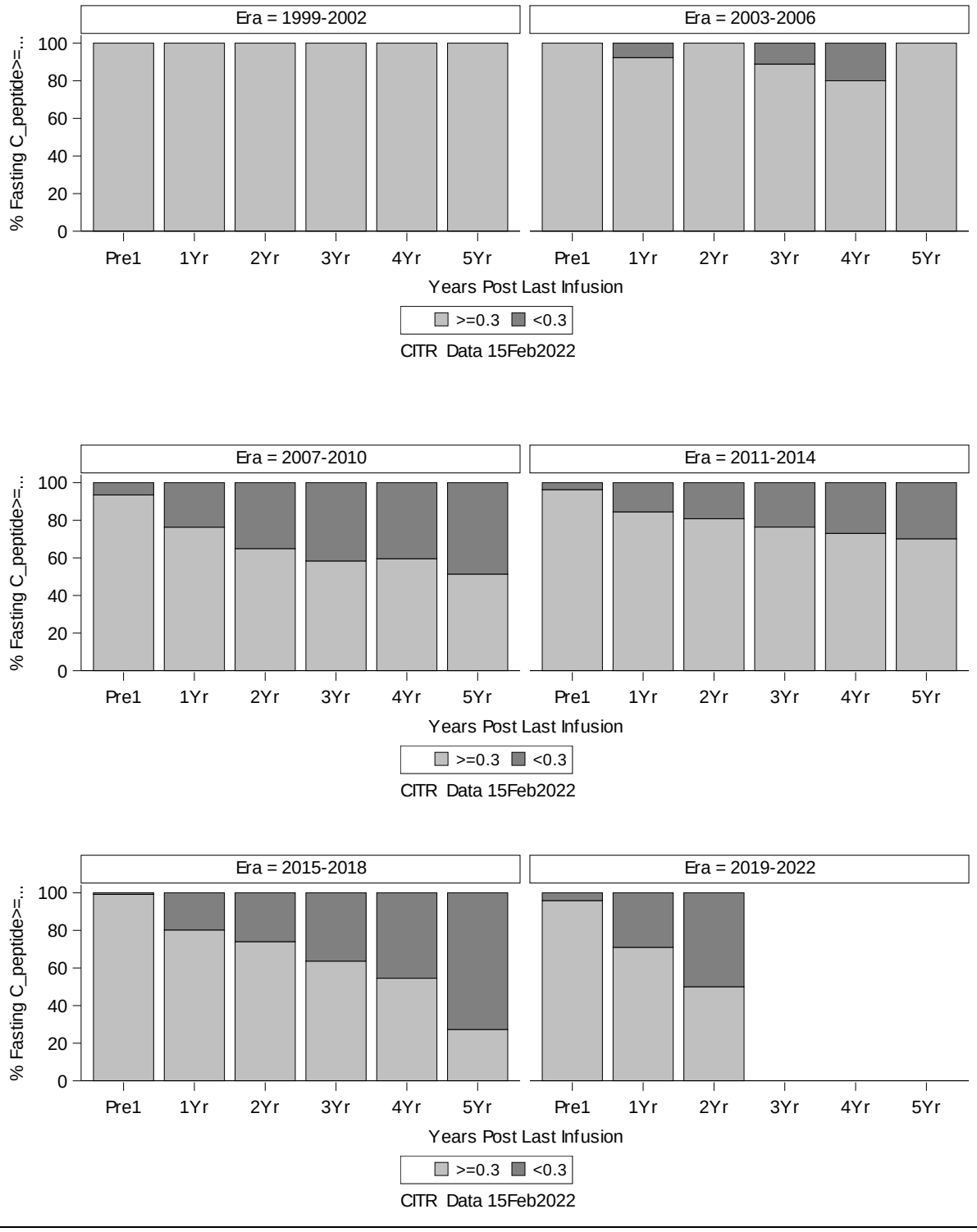
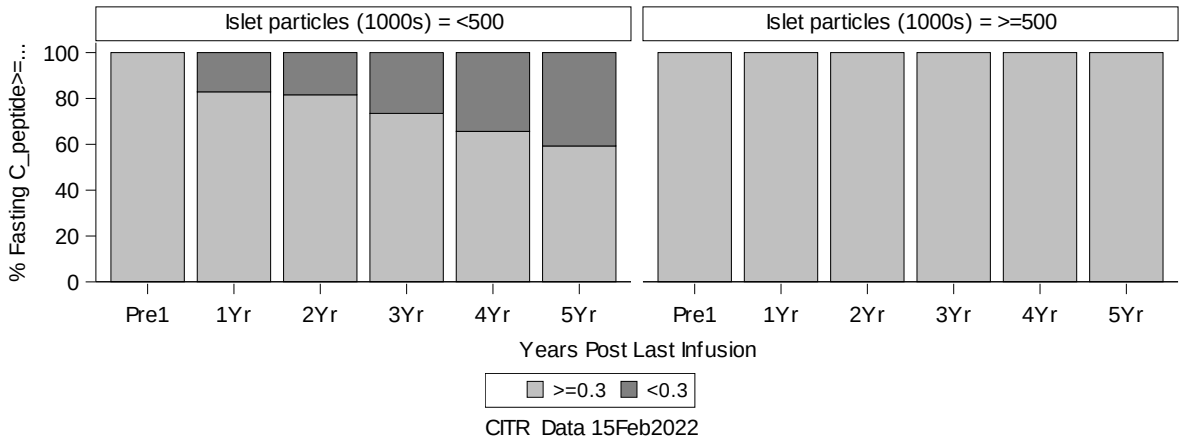
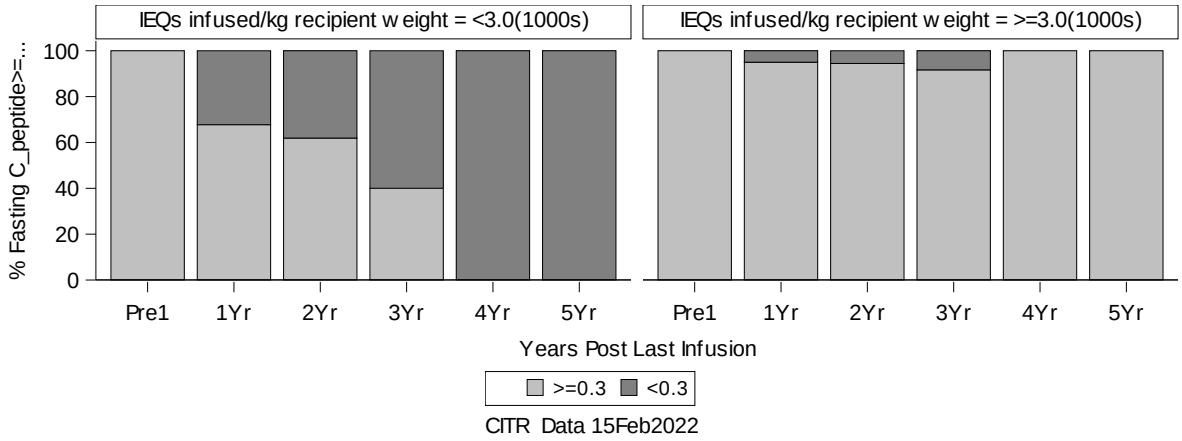


Exhibit 5 – 2C
Univariate Effects of Individual Variables (p<0.01) on Prevalence of C-peptide ≥0.3 ng/mL Post Last Infusion among Recipients 18 to 35

A. Islet particles (1000s) (p<0.0001)



B. IEQs infused/kg recipient weight (p=0.001)



C. Pancreatectomy type (p<0.0001)

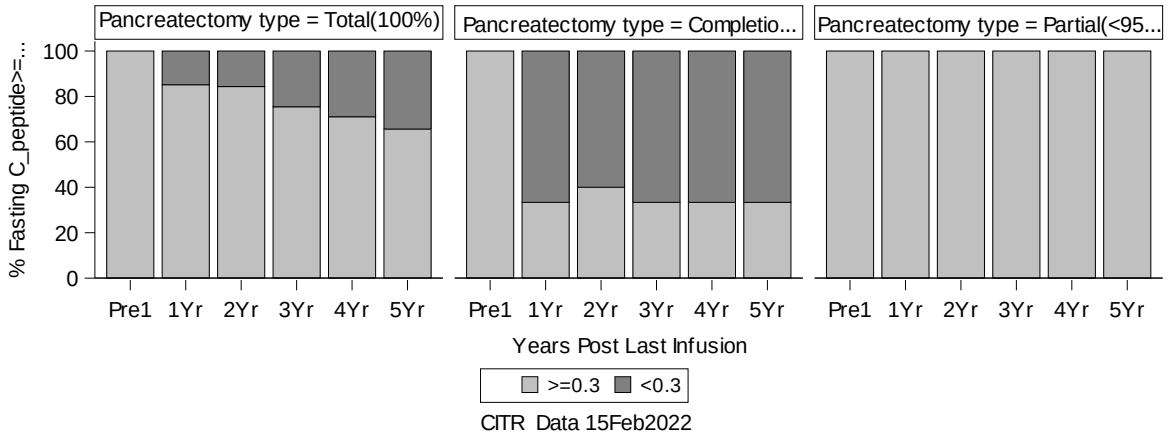


Exhibit 5 – 2C (continued)
Univariate Effects of Individual Variables (p<0.01) on Prevalence of C-peptide ≥0.3 ng/mL
Post Last Infusion among Recipients 18 to 35

D. Era (p<0.0001)

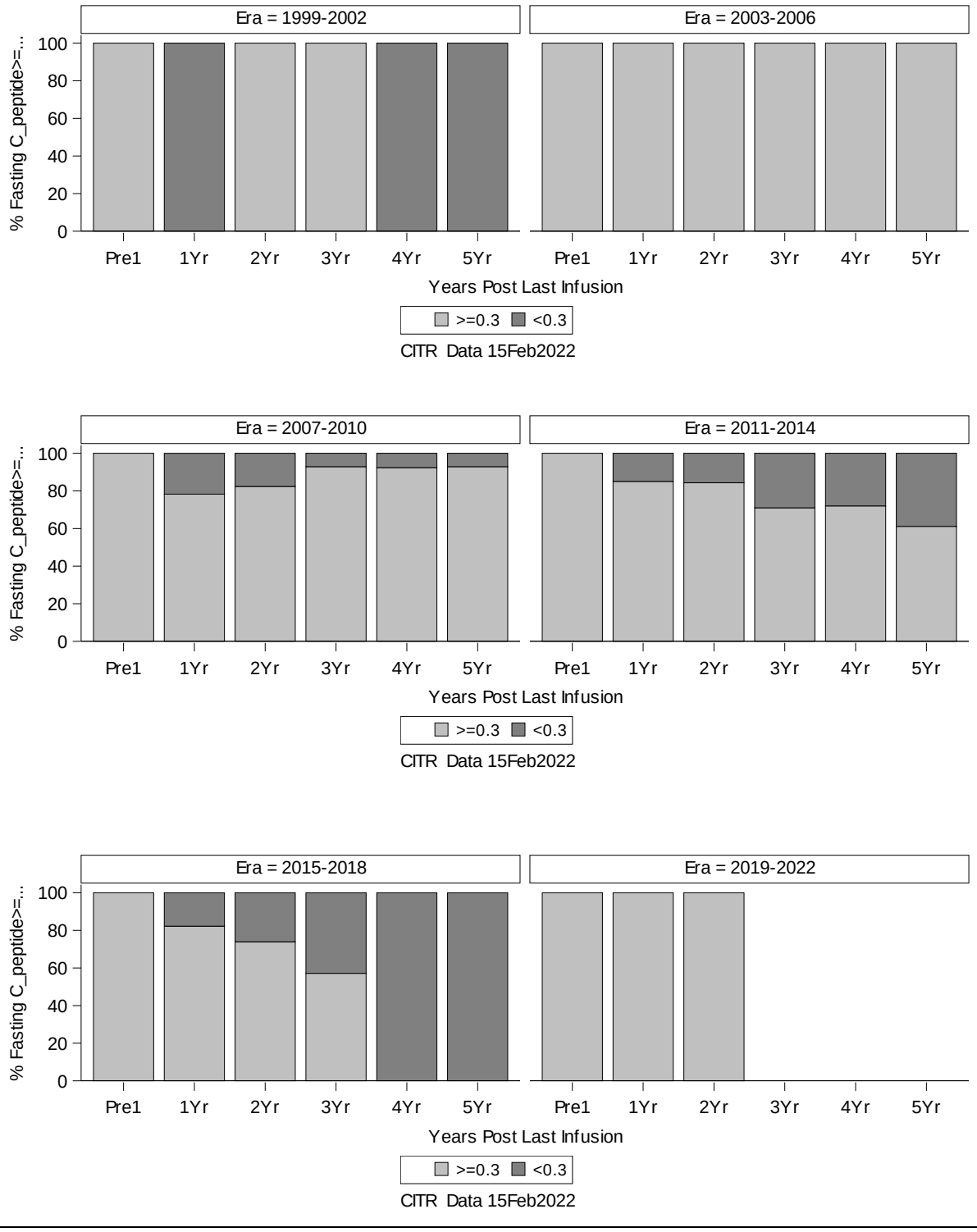


Exhibit 5 – 2D
Univariate Effects of Individual Variables (p<0.01) on Prevalence of C-peptide ≥0.3 ng/mL Post Last Infusion among Recipients 12 to 18

None

Exhibit 5 – 2E
Univariate Effects of Individual Variables (p<0.01) on Prevalence of C-peptide ≥0.3 ng/mL Post Last Infusion among Recipients 12 and under

None

Exhibit 5 – 3A
Prevalence of Fasting Blood Glucose 60-140 mg/mL Post Last Infusion by Age Group (p=0.002)

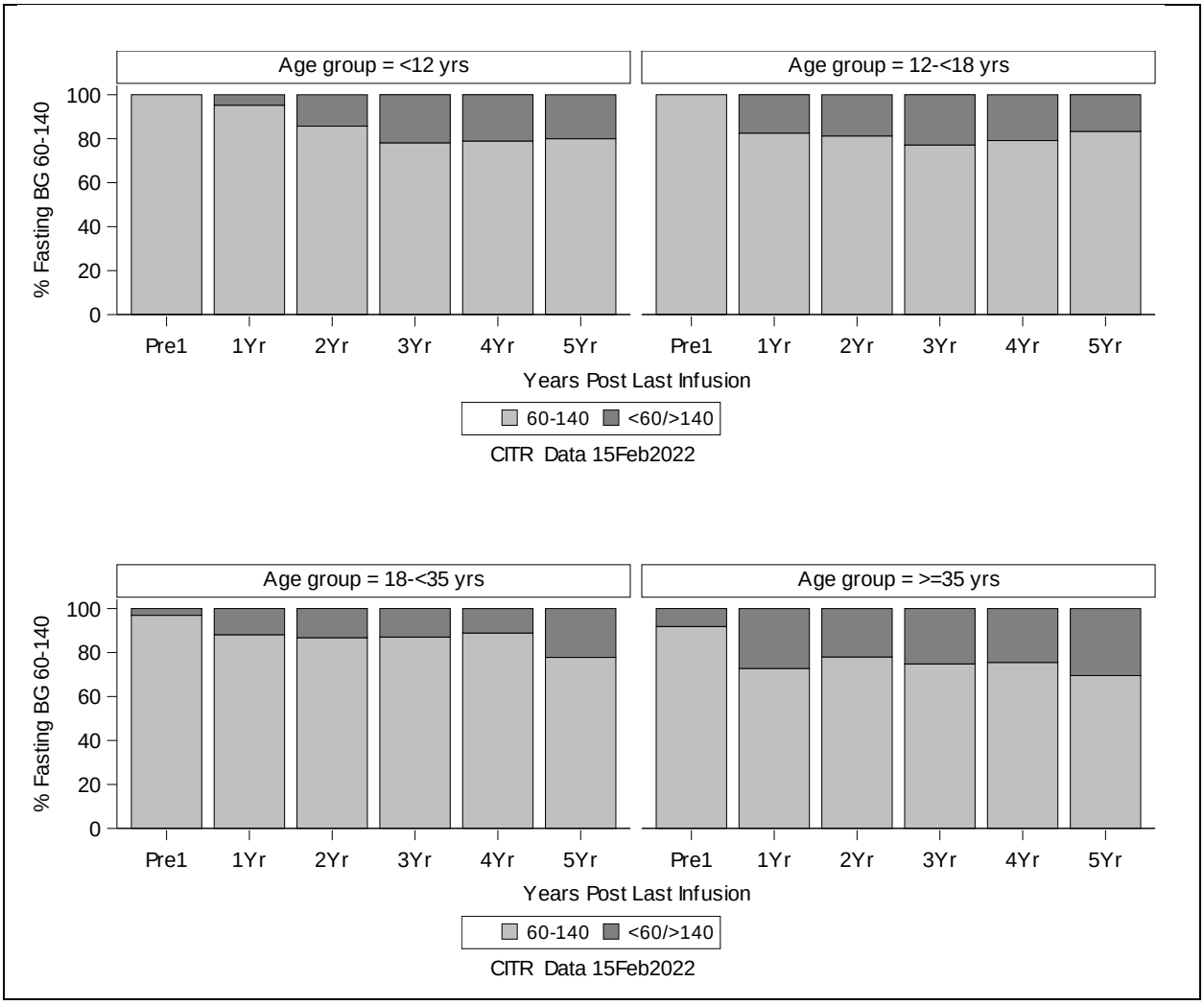
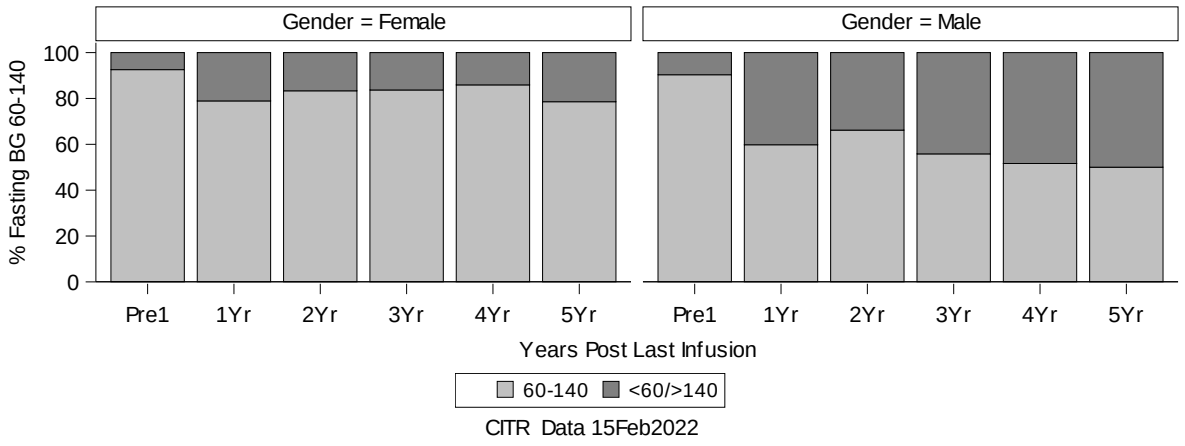
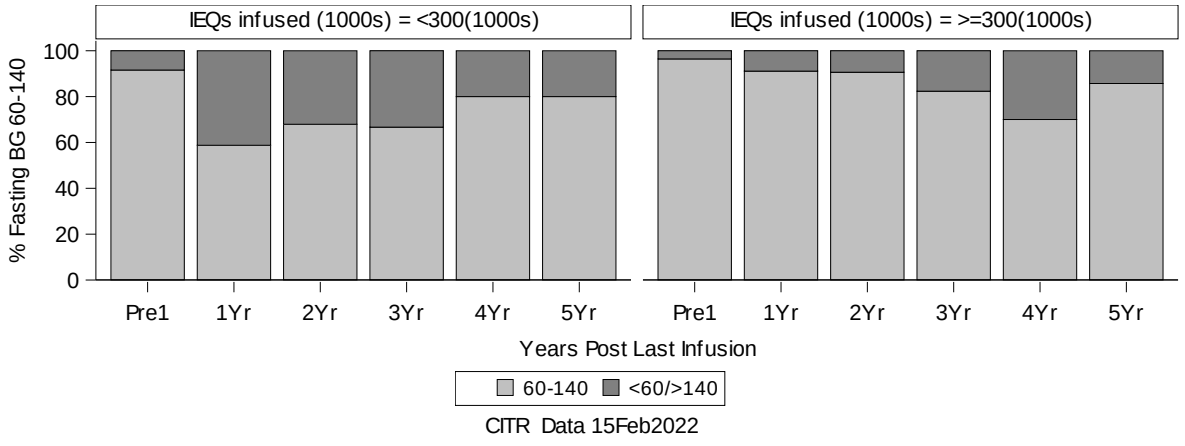


Exhibit 5 – 3B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Fasting Blood Glucose 60-140 mg/mL Post Last Infusion among Recipients 35 and over

A. Sex (p<0.0001)



B. IEQs infused (1000s) (p=0.0007)



C. Pancreatectomy type (p<0.0001)

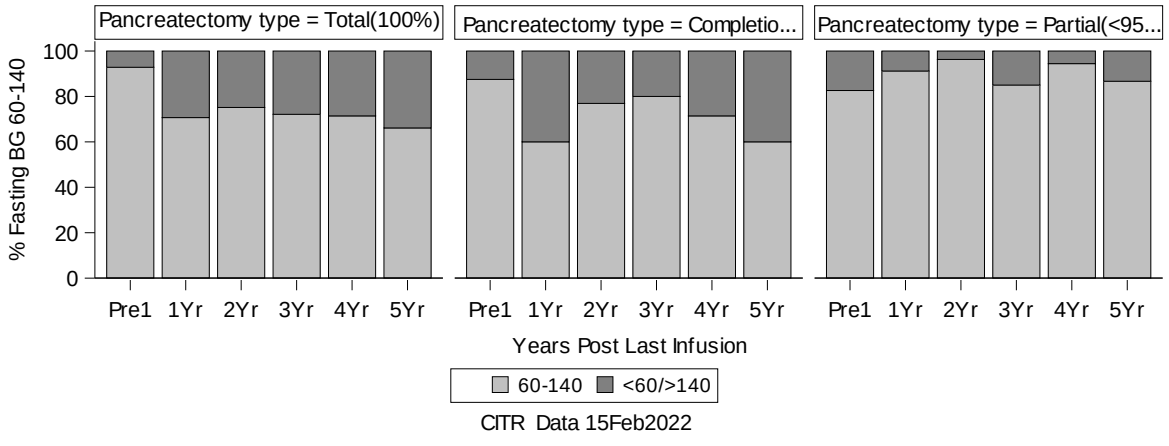


Exhibit 5 – 3C
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Fasting Blood Glucose 60-140 mg/mL Post Last Infusion among Recipients 18 to 35

None

Exhibit 5 – 3D
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Fasting Blood Glucose 60-140 mg/mL Post Last Infusion among Recipients 12 to 18

None

Exhibit 5 – 3E
Univariate Effects of Individual Variables (p<0.01) on Fasting Blood Glucose 60-140 mg/mL Post Last Infusion among Recipients 12 and under

None

Exhibit 5 – 4A

Prevalence of HbA1c<7.0% Post Last Infusion by Age Group (p=0.002)

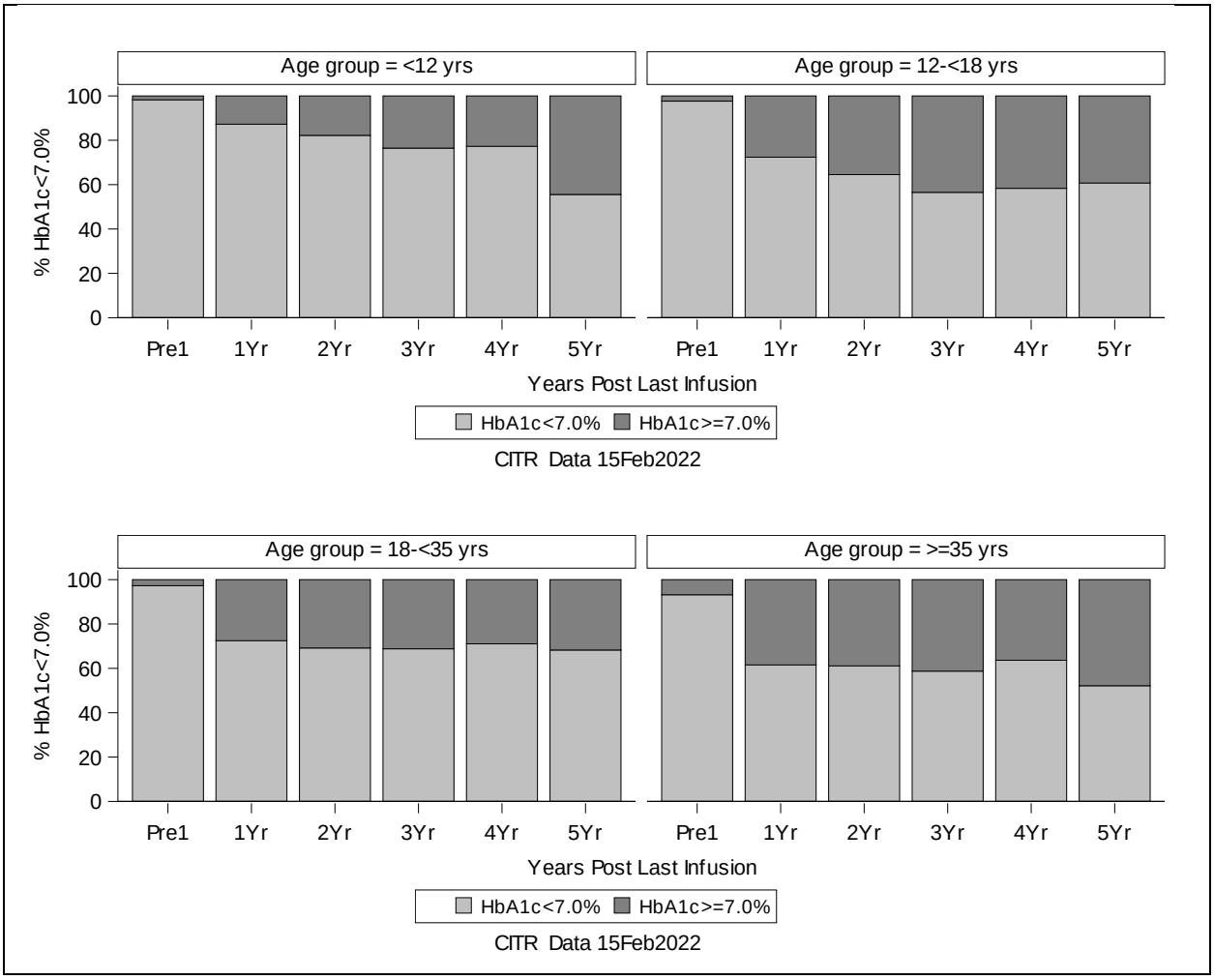
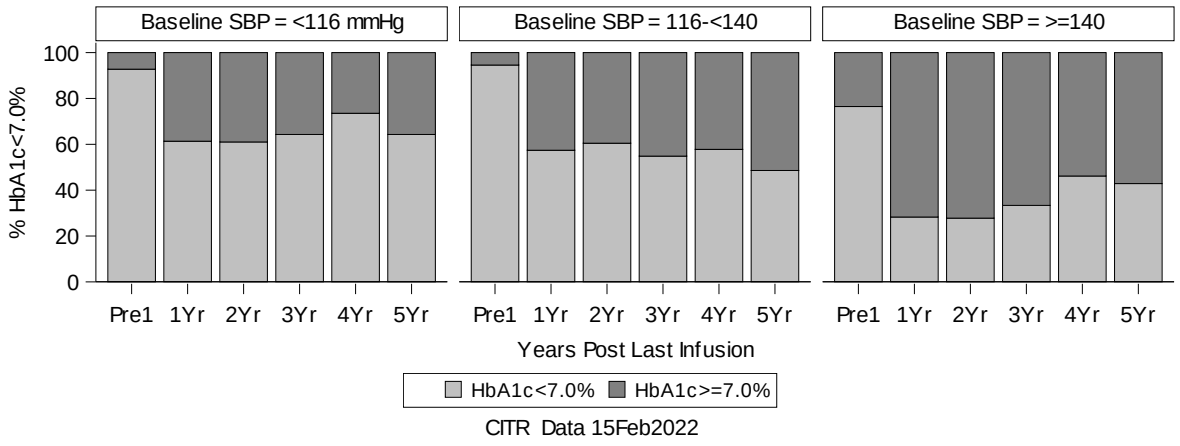
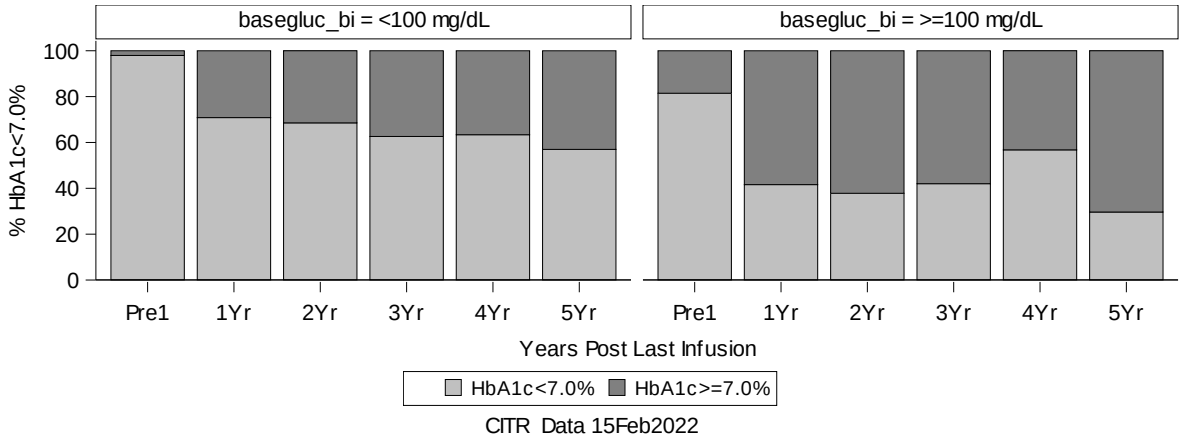


Exhibit 5 – 4B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of HbA1c<7.0% Post Last Infusion among Recipients 35 and over

A. Baseline SBP (p=0.005)



B. Baseline Fasting Blood Glucose (p<0.0001)



C. Baseline HbA1c (p=0.002)

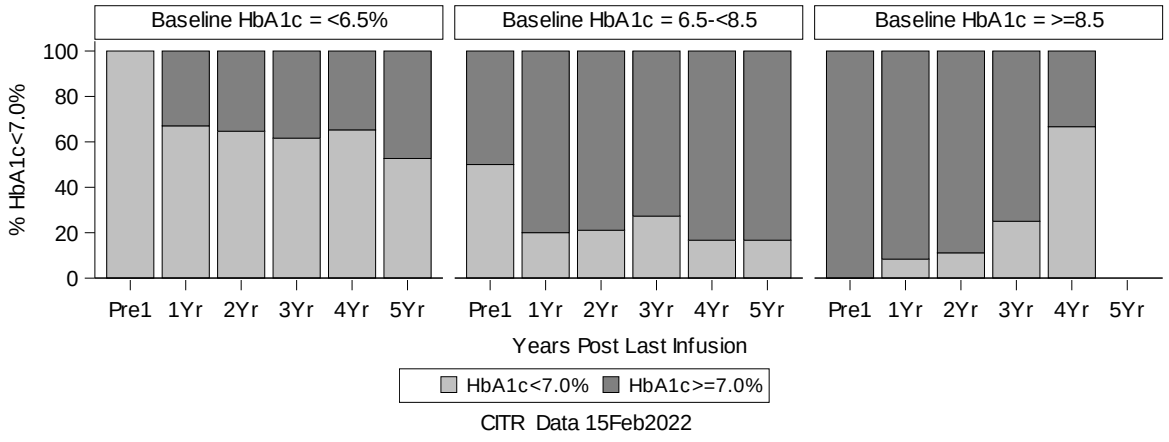
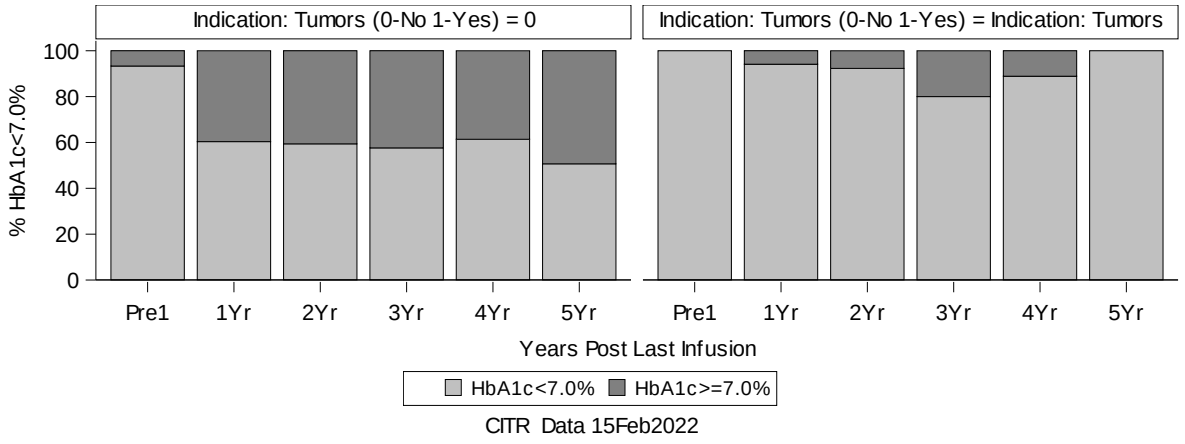


Exhibit 5 – 4B (continued)
Univariate Effects of Individual Variables (p<0.01) on Prevalence of HbA1c<7.0% Post Last Infusion among Recipients 35 and over

D. Sex (p=0.0008)

E. Indication: Tumors (p<0.0001)



F. Incubated in preservation solution (p=0.002)

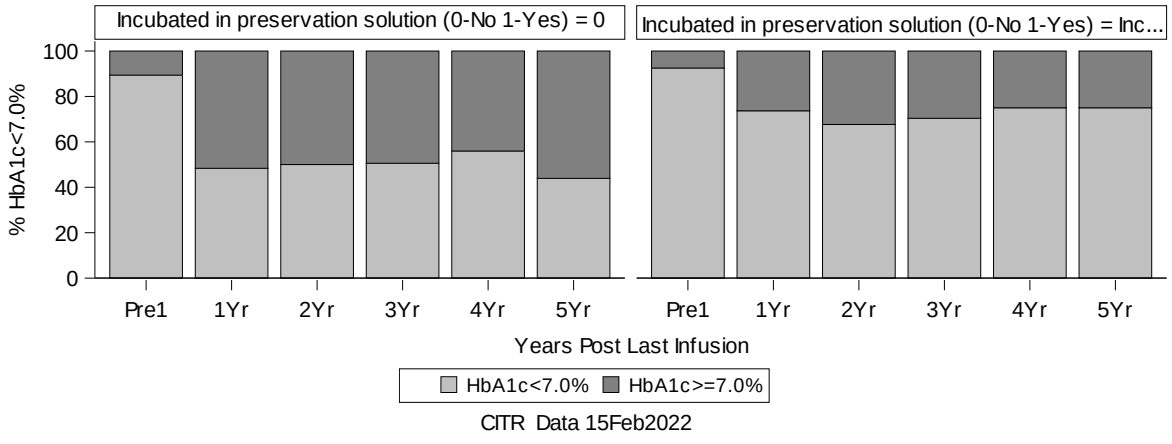
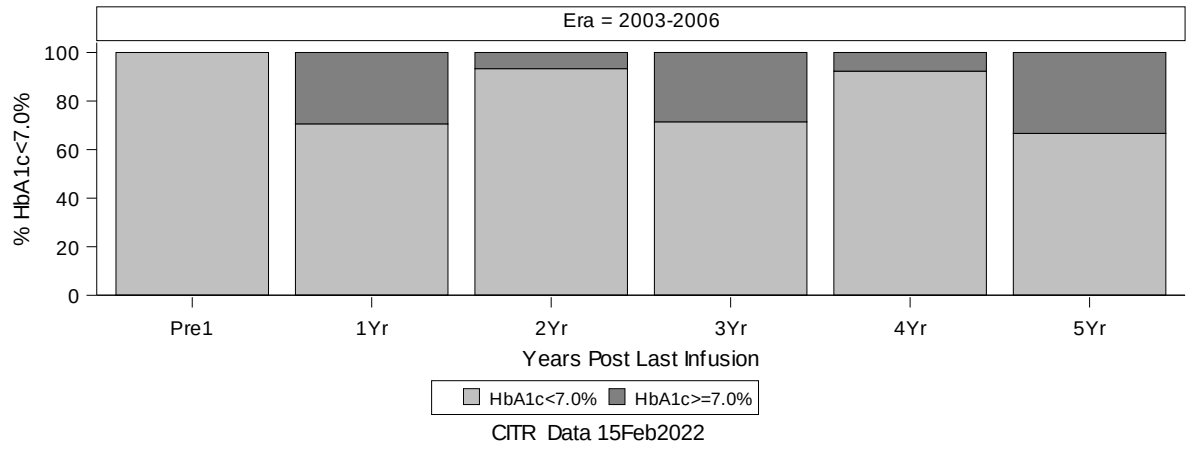
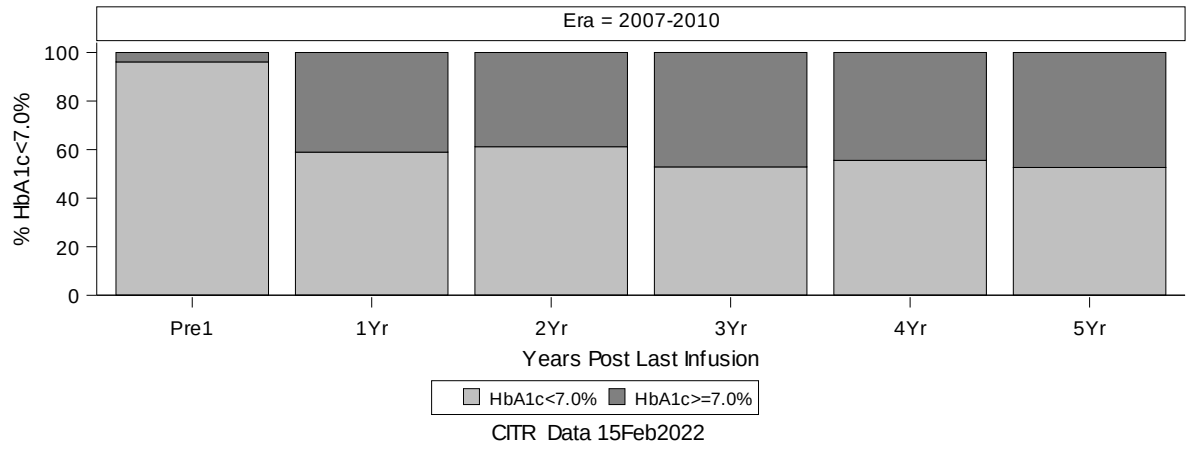


Exhibit 5 – 4B (continued)
Univariate Effects of Individual Variables (p<0.01) on Prevalence of HbA1c<7.0% Post Last Infusion among Recipients 35 and over

G. Era (p=0.002)





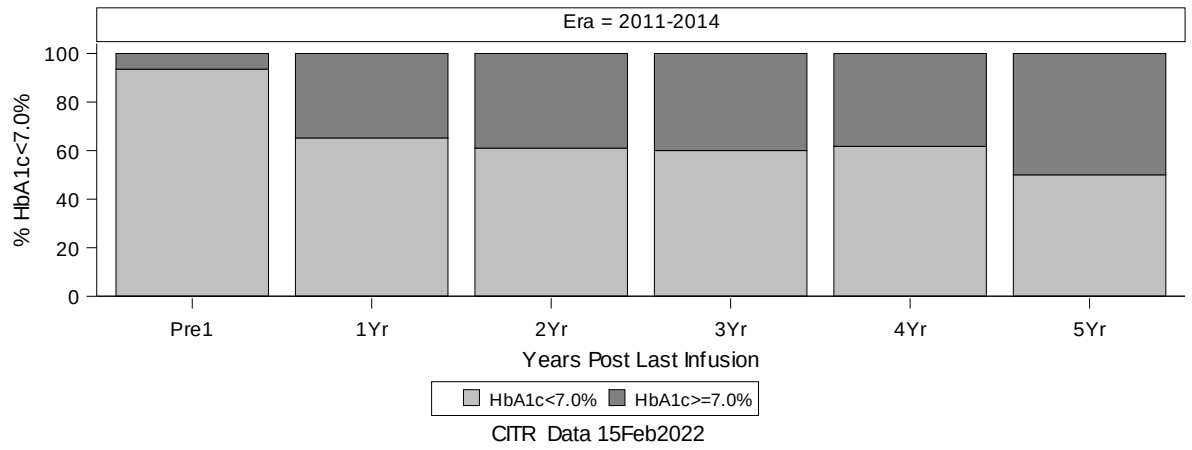


Exhibit 5 – 4B (continued)
Univariate Effects of Individual Variables (p<0.01) on Prevalence of HbA1c<7.0% Post Last Infusion among Recipients 35 and over

G. Era (p=0.002)

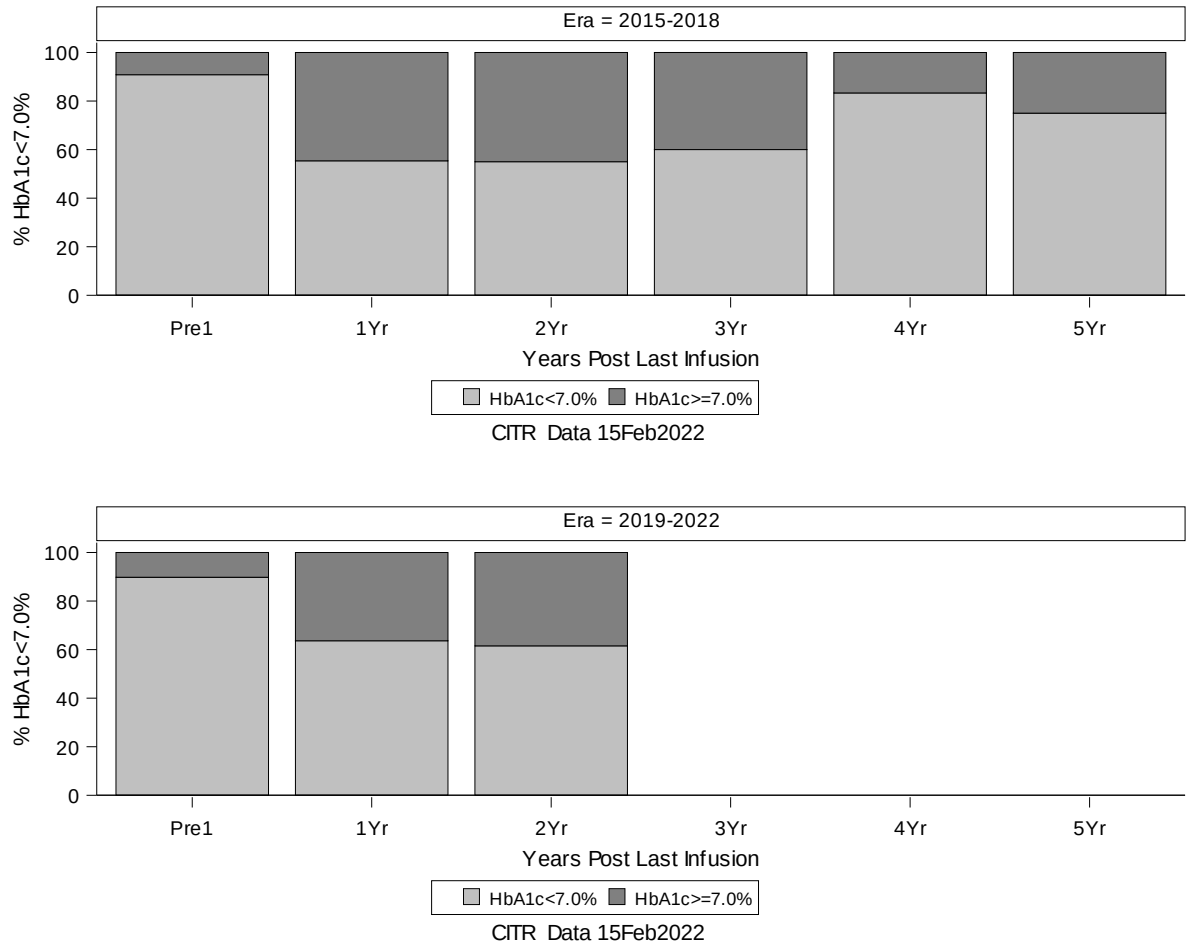
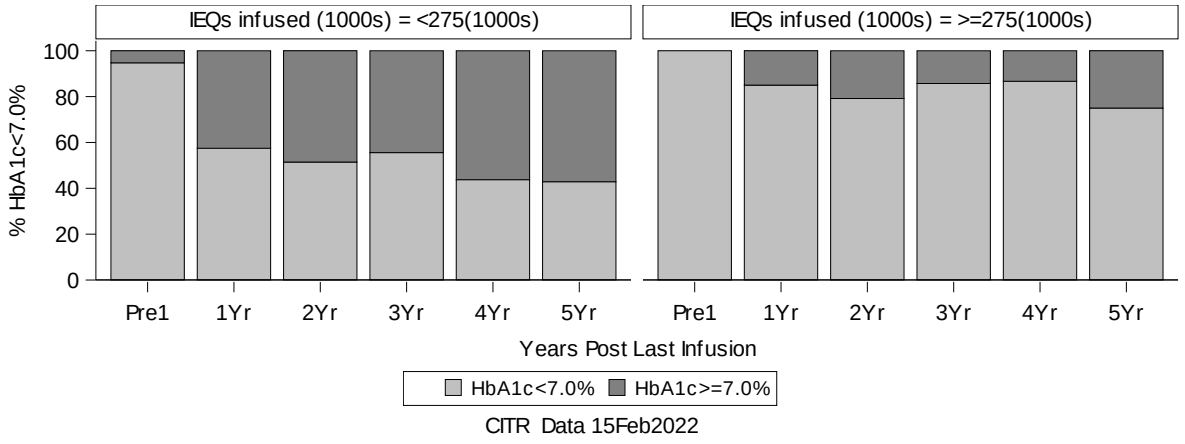


Exhibit 5 – 4C
Univariate Effects of Individual Variables (p<0.01) on Prevalence of HbA1c<7.0% Post Last Infusion among Recipients 18 to 35

A. Sex (p=0.004)

B. IEQs infused (1000s) (p=0.002)



C. IEQs infused/kg recipient weight (p=0.001)

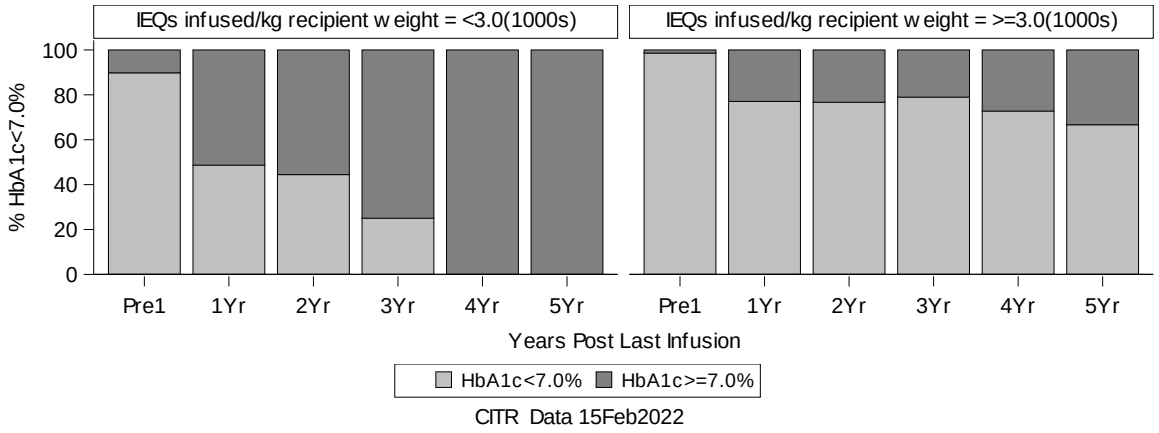


Exhibit 5 – 4C (continued)
Univariate Effects of Individual Variables (p<0.01) on Prevalence of HbA1c<7.0% Post Last Infusion among Recipients 18 to 35

D. Pancreatectomy type (p<0.0001)

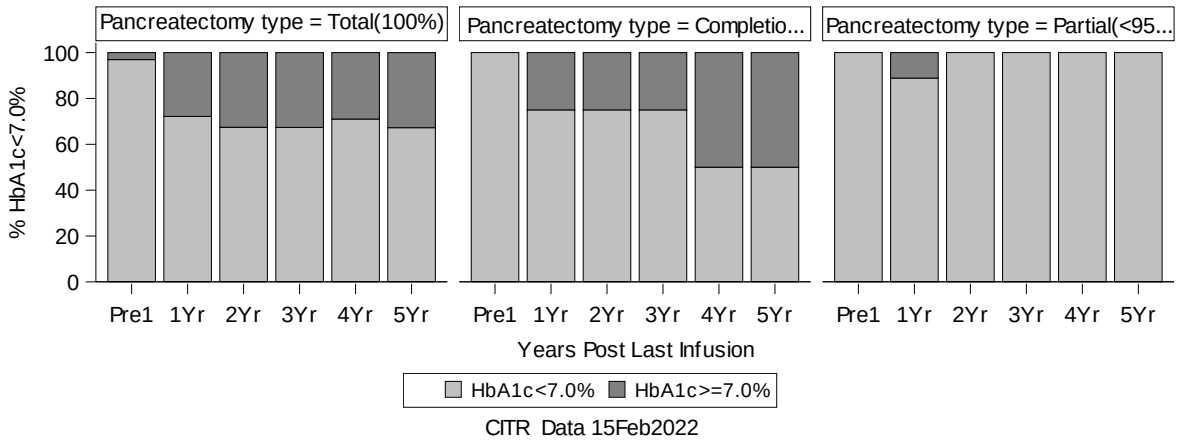


Exhibit 5 – 4D
Univariate Effects of Individual Variables (p<0.01) on Prevalence of HbA1c<7.0% Post Last Infusion among Recipients 12 to 18

None

Exhibit 5 – 4E (continued)
Univariate Effects of Individual Variables (p<0.01) on HbA1c<7.0% Post Last Infusion among Recipients 12 and under

None

Exhibit 5 – 5
Prevalence of Absence of Severe Hypoglycemic Events Post Last Infusion by Age Group (p<0.0001)

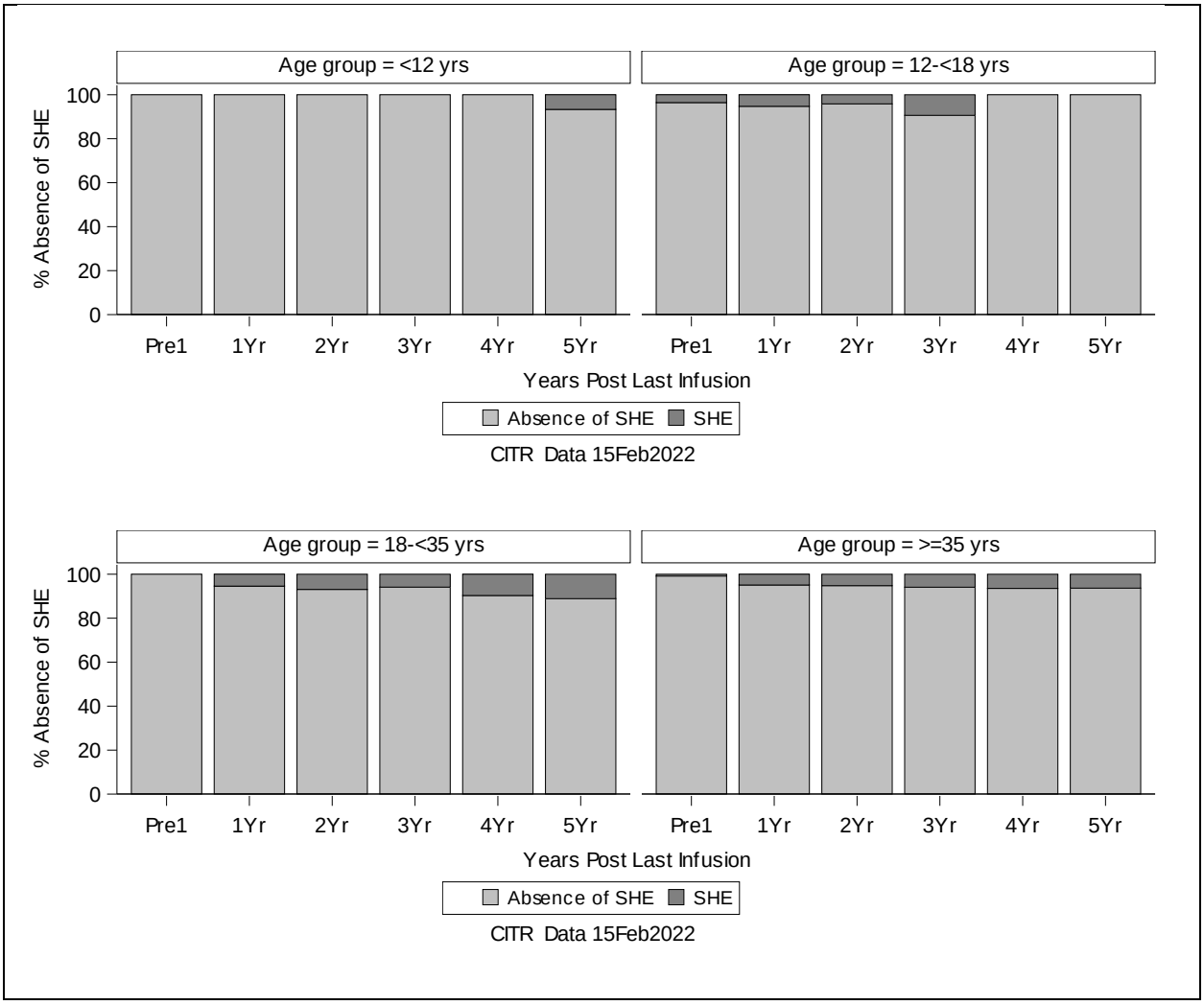
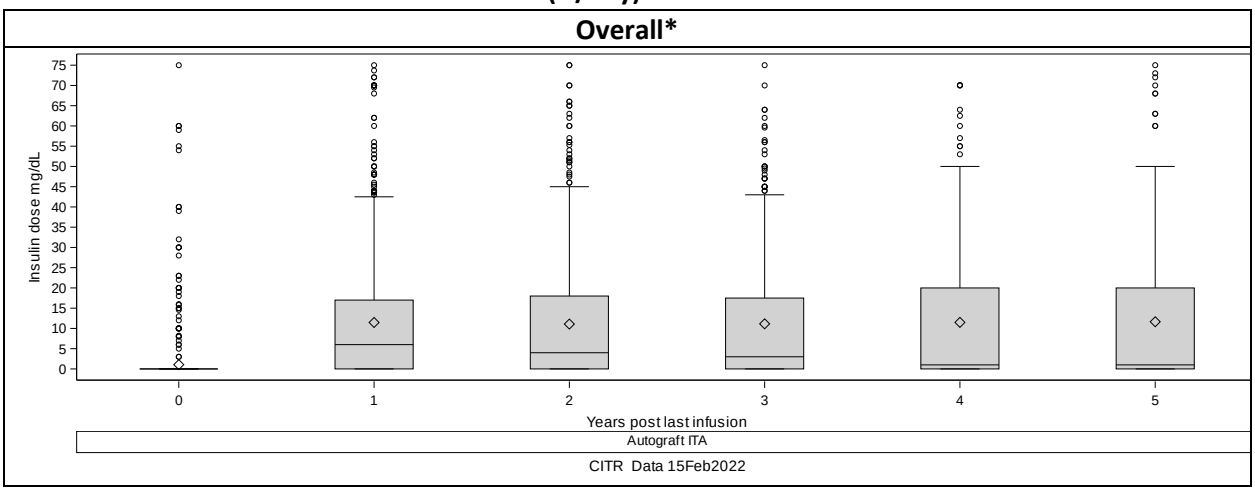


Exhibit 5 – 6

Insulin Dose (U/day) Post Last Infusion



***No factors significant at p<0.01**

Exhibit 5 – 7

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

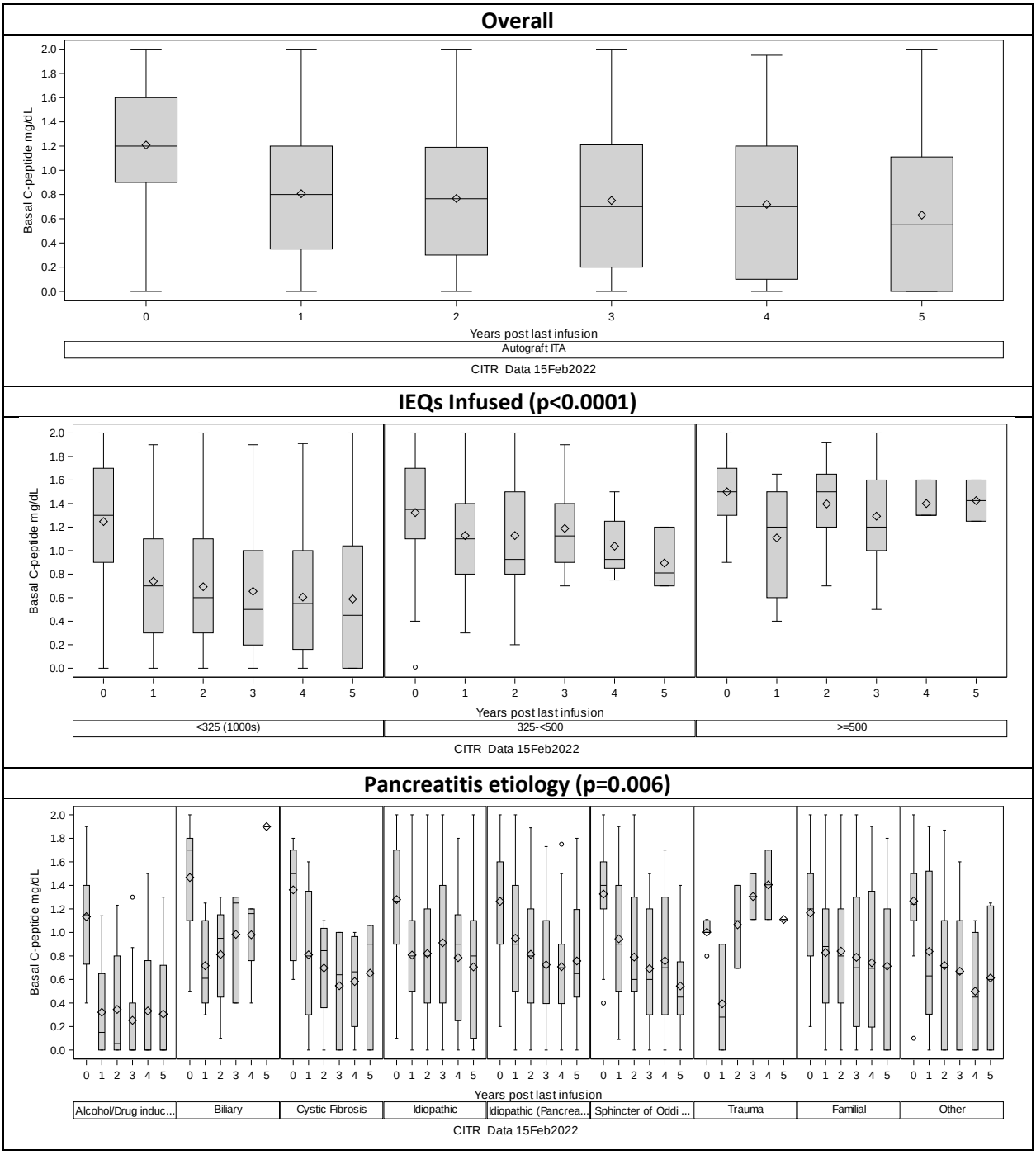


Exhibit 5 – 8

HbA1c (%) Post Last Infusion

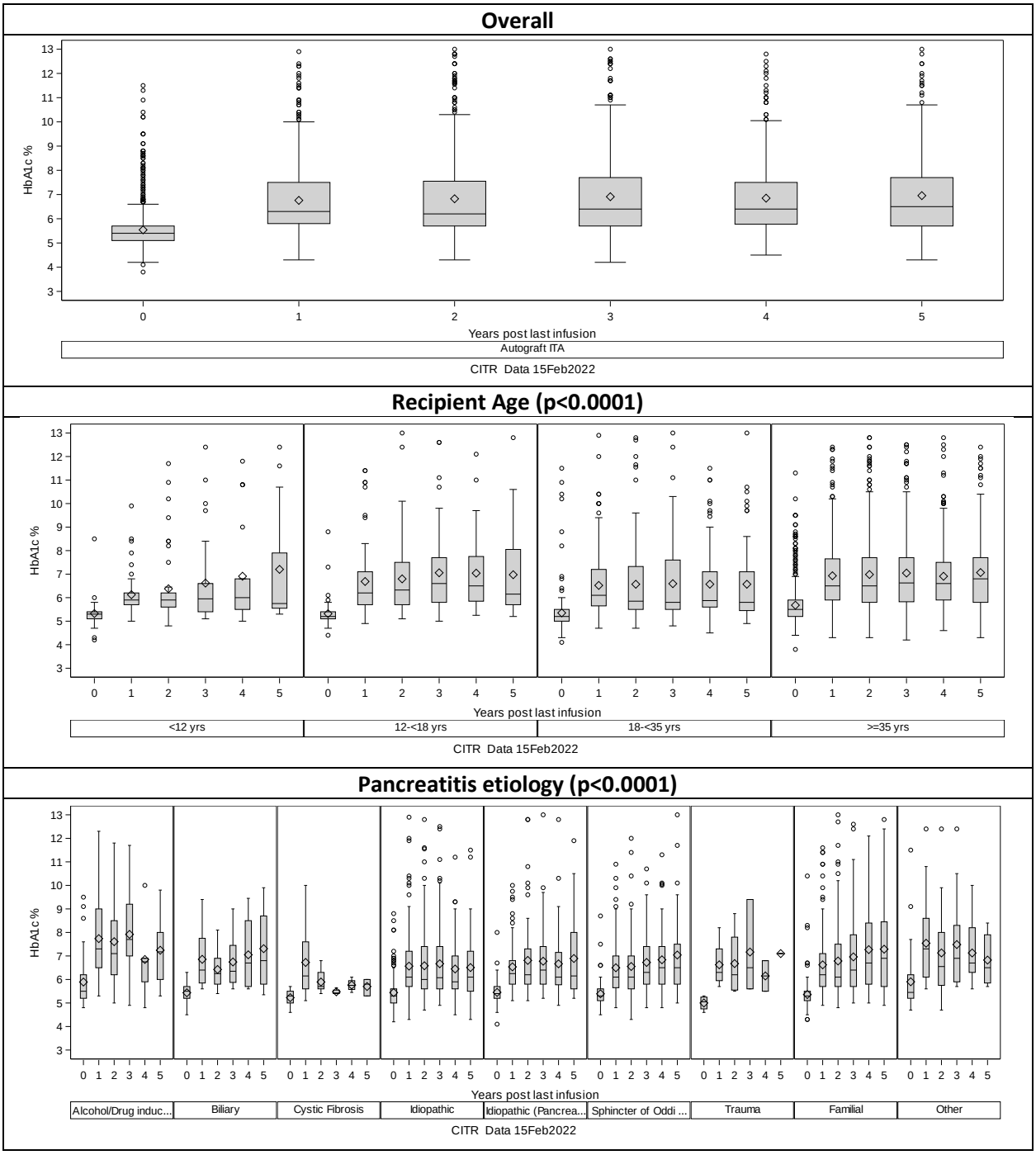
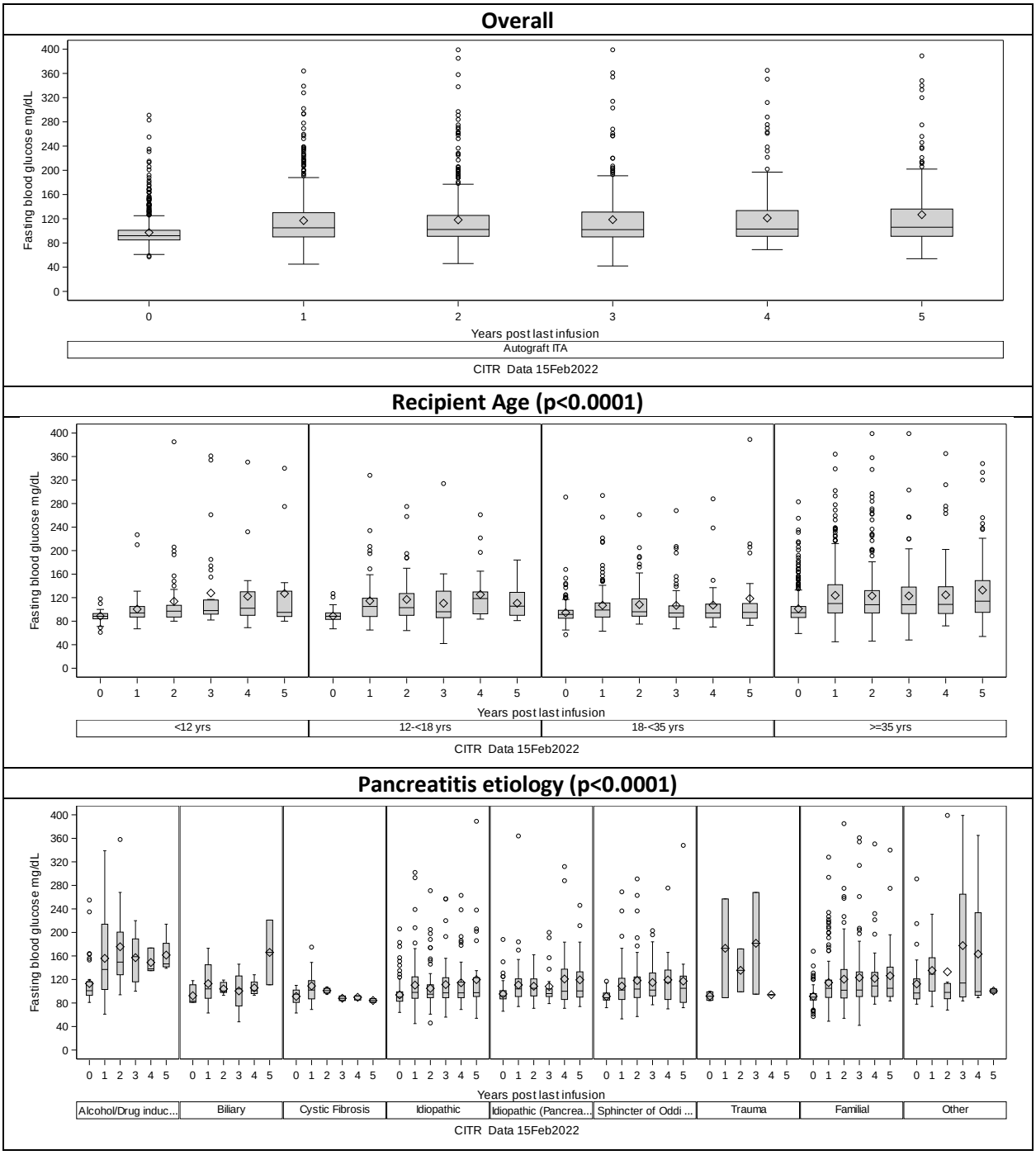


Exhibit 5 – 9

Fasting Blood Glucose (mg/dL) Post Last Infusion



Appendix A: Autograft Islet Transplant Center Contributors

(Centers and Staff are listed in alphabetical order)
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Appendix A: Autologous Islet Transplant Center Contributors *(continued)*

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

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Ling-jia Wang

Appendix A: Autologous Islet Transplant Center Contributors *(continued)*

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

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Caitlin Winkler

Appendix A: Autologous Islet Transplant Center Contributors *(continued)*

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

CITR Coordinating Center

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Chirag Desai
Thomas Eggerman
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Andrew Posselt
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Co-Chair: Melena Bellin
Vice Chair: Rodolfo Alejandro
Guillermo Arreaza-Rubin
Thomas Eggerman
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Jeff Mitchell
Elizabeth Payne
Michael Rickels

Publications and Presentations Committee

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Data Elements Committee

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Thomas Eggerman
Tatsuya Kin
Bashoo Naziruddin
Klearchos Papas
James Shaw

Appendix A: Autologous Islet Transplant Center Contributors *(continued)*

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

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Kirstie Danielson
Amna Daud
Jasmine Davis
Riya Devani
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Laure Nasse
David Baidal
Mary Baldecch
Lenka Nemetova
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Sachiko Paz
Laurencia Perea
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Margaret Thomas
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