Inaugural Report on Autologous Islet Transplantation

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

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

January 6, 2017
Collaborative Islet Transplant Registry 2016

Islet Autografts

Yellow: insulin independent; Green: insulin-using with graft function;
Black: no islet function (C-peptide<0.3 ng/ml); Gray: missing data; Red: re-infusions.
Pie charts show percent of all follow-up time.
23 August 2018

MEMORANDUM

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

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

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

SUBJECT: CITR Inaugural Report on Autologous Islet Transplantation

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

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

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

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

The CITR Inaugural Report on Autologous Islet Transplantation details data received as of January 6, 2017 for all auto-islet transplant recipients transplanted by September 15, 2016.

Detailed Methods and Definitions can be found in the CITR 10th Annual Report at www.citregistry.org
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Introduction

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

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

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

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

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

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

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<thead>
<tr>
<th>CITR-Consented AUTO Recipients</th>
<th>North America</th>
<th>Europe</th>
<th>Australia</th>
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<tr>
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Exhibit 1-1B
Auto-Islet Infusions

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<th>Adult</th>
<th>Total Infusions</th>
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<td>Europe/ Australia</td>
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<td>96</td>
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<td>665</td>
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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

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<tr>
<td>2015</td>
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Legend:
- All North American centers ever performing islet autografts 1999-2015 (N=23)
- CITR-participating centers with data reported (N=11)

CITR Data 06 Jan 2017
Exhibit 1-4A
New islet autograft transplant enrollment, by year of first transplant – North America

<table>
<thead>
<tr>
<th>Year</th>
<th>All autograft recipients</th>
<th>Registered in CITR</th>
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<td>2015</td>
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CITR Data 06 Jan 2017

Note: The data represents new islet autograft transplant enrollment in North America, with a focus on the number of recipients by year of first transplant.
Exhibit 1-4B
New islet autograft transplant enrollment, by year of first transplant – Europe and Australia

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<tr>
<td>2015</td>
<td>6</td>
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</table>

Autograft recipients registered in CITR (N= 65)
CITR Data 06Jan2017
Exhibit 1-5
First and second autograft transplants, by year of transplant

Year

Infusion Sequence
1 2

CITR Data 06Jan2017
Exhibit 1-6
Adult and pediatric autograft transplants, by year of transplant
Chapter 2
Autologous Islet Recipient Characteristics
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Introduction

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

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

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

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

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

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

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

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

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

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

Any nominal differences in the laboratory values by age or era are based on too small a sample for any meaningful interpretation (Exhibit 2-5).
Exhibit 2-1
Recipient Demographics

<table>
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<tr>
<th>Gender</th>
<th>Age Group</th>
<th>N</th>
<th>%</th>
<th>N</th>
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Recipient Demographics

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Exhibit 2-1 (continued)
Recipient Demographics

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## Exhibit 2-1 (continued)

### Recipient Demographics

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#### Era

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### Ethnicity

#### Chart: Data completeness by gender and age group

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

---

### Chart: Data completeness by gender and era

- **1999-2002**
- **2003-2006**
- **2007-2010**
- **2011-2014**
- **2015-2018**

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**CTR Data 06Jan2017**
### Exhibit 2-2
Recipient Characteristics at First Infusion

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<td>N Mean SE</td>
<td>N Mean SE</td>
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<td>62 15.4 0.2</td>
<td>216 27.7 0.3</td>
<td>507 48.3 0.4</td>
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<tr>
<td>Weight (kg)</td>
<td>3 39.1 5.2</td>
<td>5 50.2 7.7</td>
<td>67 73.9 2.3</td>
<td>212 71.6 1.1</td>
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<tr>
<td>Body Mass Index (kg/m²)</td>
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<td>Daily insulin requirement prior to infusion (units)</td>
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<td>391 1.3 0.4</td>
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<td>Fasting plasma glucose (mg/dL)</td>
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<td>235 98.3 1.5</td>
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<td>Basal C-Peptide (ng/mL)</td>
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Exhibit 2-2 (continued)
Recipient Characteristics at First Infusion

- **Age at transplant**
  - **Age Group**
    - <12 yrs
    - 12-<18 yrs
    - 18-<35 yrs
    - >=35 yrs
  - **Era**
    - 1999-2002
    - 2003-2006
    - 2007-2010
    - 2011-2014
    - 2015-2018

- **Weight (kg)**
  - **Age Group**
    - <12 yrs
    - 12-<18 yrs
    - 18-<35 yrs
    - >=35 yrs
  - **Era**
    - 1999-2002
    - 2003-2006
    - 2007-2010
    - 2011-2014
    - 2015-2018

- **BMI (kg/m²)**
  - **Age Group**
    - <12 yrs
    - 12-<18 yrs
    - 18-<35 yrs
    - >=35 yrs
  - **Era**
    - 1999-2002
    - 2003-2006
    - 2007-2010
    - 2011-2014
    - 2015-2018

CITR Data 06Jan2017

**Chapter 2**

Page 2-8
Exhibit 2-2 (continued)
Recipient Characteristics at First Infusion

Pre-tx insulin (units)

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Avg daily ins/kg

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Fast gluc(mg/dL)

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

- Basal C-Peptide (ng/mL)
- Era

- HbA1c (%)
- Age Group

CITR Data 06Jan2017
### Exhibit 2-2B
Recipient Insulin Use at First Infusion

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Recipient Characteristics and Medical History

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#### Era

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#### Severe Hypoglycemic Events

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

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| Lipid-lowering medication | Era                        |                   |                   |                   |                   |                   |                   |                   |                   |
|---------------------------|----------------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|
|                           | N   | %   | N   | %   | N   | %   | N   | %   | N   | %   | p   |
| Lipid-lowering medication | No  | 4   | 100.0 | 1    | 50.0  | 34   | 79.1 | 129  | 86.6 | 20  | 95.2  |
|                           | Yes | 0.0 | 0.0   | 1    | 50.0  | 9    | 20.9 | 20   | 13.4 | 1   | 4.8   |

| Lipid-lowering medication | Era                        |                   |                   |                   |                   |                   |                   |                   |                   |
|---------------------------|----------------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|
| Lipid-lowering medication | Missing | 32  | 88.9  | 83   | 97.6  | 233  | 84.4 | 225  | 60.2 | 27  | 56.3  |
|                           | Available | 4   | 11.1  | 2    | 2.4   | 43   | 15.6 | 149  | 39.8 | 21  | 43.8  |

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

#### Lipid-lowering medication

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

CITR Data 06Jan2017
**Exhibit 2-3 (continued)**

**Recipient Diabetes Characteristics and Medical History**

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

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"CITR 1st Annual Autograft Report"
Exhibit 2-3 (continued)

Recipient Diabetes Characteristics and Medical History

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## Exhibit 2-3 (continued)

### Recipient Diabetes Characteristics and Medical History

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Recipient Diabetes Characteristics and Medical History

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Recipient Diabetes Characteristics and Medical History

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Recipient Diabetes Characteristics and Medical History

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**Recipient Diabetes Characteristics and Medical History**

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CITR 1st Annual Autograft Report

Datafile Closure: January 6, 2017

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

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**Recipient Diabetes Characteristics and Medical History**

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Recipient Diabetes Characteristics and Medical History

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

#### Prior surgical procedure - Puestow

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![Graph of Prior surgical procedure - Puestow](CITR_Data_06Jan2017)
### Exhibit 2-3 (continued)

**Recipient Diabetes Characteristics and Medical History**

#### Prior Surgical Procedure - Traversal

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**Recipient Diabetes Characteristics and Medical History**

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**Recipient Diabetes Characteristics and Medical History**

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<td>162 (49.8%)</td>
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#### Era

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

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**Graphs**

- **Graph 1:** Prior surgical procedure- Other by age group.
- **Graph 2:** Prior surgical procedure- Other by era.

---

*CITR 1st Annual Autograft Report*  
Datafile Closure: January 6, 2017  
Chapter 2  
Page 2-31
### Exhibit 2-3 (continued)

**Recipient Diabetes Characteristics and Medical History**

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Recipient Pancreatectomy Information

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### Exhibit 2-4 (continued)

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**Exhibit 2-4 (continued)**

**Recipient Pancreatectomy Information**

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Exhibit 2-4 (continued)
Recipient Pancreatectomy Information

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Exhibit 2-4 (continued)
Recipient Pancreatectomy Information

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**Exhibit 2-4 (continued)**

Recipient Pancreatectomy Information

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

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**Pancreatectomy for treating chronic pancreatitis**

- **<12 yrs**: N=1, %25.0
- **12-<18 yrs**: N=5, %55.6
- **18-<35 yrs**: N=12, %24.5
- **>=35 yrs**: N=62, %35.6

**Pancreatectomy for treating chronic pancreatitis**

- **2003-2006**: N=2, %100.0
- **2007-2010**: N=53, %85.5
- **2011-2014**: N=167, %77.3
- **2015-2018**: N=333, %65.7

**Pancreatectomy for treating chronic pancreatitis**

- **1999-2002**: N=36, %100.0
- **2003-2006**: N=83, %97.6
- **2007-2010**: N=240, %87.0
- **2011-2014**: N=222, %59.4
- **2015-2018**: N=2, %4.2

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CITR 1st Annual Autograft Report

Datafile Closure: January 6, 2017

Chapter 2
### Exhibit 2-4 (continued)

**Recipient Pancreatectomy Information**

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

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![Pancreatectomy for treating acute pancreatitis](attachment:image1.png)

**CITR Data 06Jan2017**

---

![Pancreatectomy for treating acute pancreatitis](attachment:image2.png)

**CITR Data 06Jan2017**
Exhibit 2-4 (continued)
Recipient Pancreatectomy Information

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Recipient Pancreatectomy Information

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

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**Pancreatectomy for treating infection**

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

- **2003-2006**
- **2007-2010**
- **2011-2014**
- **2015-2018**

**CITR Data 06Jan2017**
## Exhibit 2-4 (continued)

### Recipient Pancreatectomy Information

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| Pancreatectomy for treating Other Missing | 30 | 88.2 | 53 | 85.5 | 166 | 76.9 | 323 | 63.7 |
| Available | 4 | 11.8 | 9 | 14.5 | 50 | 23.1 | 184 | 36.3 |

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<td>N</td>
<td>%</td>
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| Pancreatectomy for treating Other No | 0.0 | 2 | 28.6 | 34 | 81.0 | 142 | 94.7 | 45 | 97.8 | *** |
| Yes | 2 | 100.0 | 5 | 71.4 | 8 | 19.0 | 8 | 5.3 | 1 | 2.2 |

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| Pancreatectomy for treating Other Missing | 34 | 94.4 | 78 | 91.8 | 234 | 84.8 | 224 | 59.9 | 2 | 4.2 |
| Available | 2 | 5.6 | 7 | 8.2 | 42 | 15.2 | 150 | 40.1 | 46 | 95.8 |

*=p<.05; **=p<.01; ***=p<.001
### Recipient Pancreatectomy Information

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<td>SE</td>
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<td>N  Mean</td>
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### Exhibit 2-4 (continued)
Recipient Pancreatectomy Information

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Exhibit 2-4 (continued)
Recipient Pancreatectomy Information

Pancreatitis etiology

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CITR Data 06Jan2017

Pancreatitis etiology

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CITR Data 06Jan2017
Pancreatitis etiology

Era

- 2015-2018
  - Alcohol/Drug induced: 100%
  - Idiopathic: 100%
  - Idiopathic (Pancreas divisum): 100%
  - Biliary: 100%
  - Sphincter of Oddi Dysfunction (SOD): 100%
  - Other: 100%
  - Familial: 100%
- 2011-2014
  - Alcohol/Drug induced: 100%
  - Idiopathic: 100%
  - Idiopathic (Pancreas divisum): 100%
  - Biliary: 100%
  - Sphincter of Oddi Dysfunction (SOD): 100%
  - Other: 100%
  - Familial: 100%
- 2007-2010
  - Alcohol/Drug induced: 100%
  - Idiopathic: 100%
  - Idiopathic (Pancreas divisum): 100%
  - Biliary: 100%
  - Sphincter of Oddi Dysfunction (SOD): 100%
  - Other: 100%
  - Familial: 100%
- 2003-2006
  - Alcohol/Drug induced: 100%
  - Idiopathic: 100%
  - Idiopathic (Pancreas divisum): 100%
  - Biliary: 100%
  - Sphincter of Oddi Dysfunction (SOD): 100%
  - Other: 100%
  - Familial: 100%
- 1999-2002
  - Alcohol/Drug induced: 100%
  - Idiopathic: 100%
  - Idiopathic (Pancreas divisum): 100%
  - Biliary: 100%
  - Sphincter of Oddi Dysfunction (SOD): 100%
  - Other: 100%
  - Familial: 100%

Age Group

- <12 yrs: 100%
- 12-<18 yrs: 100%
- 18-<35 yrs: 100%
- >=35 yrs: 100%

CITR Data 06Jan2017
### Exhibit 2-5

**Recipient Laboratory Values at First Infusion**

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<td>SE</td>
<td>N</td>
<td>Mean</td>
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<td>HDL (mg/dL)</td>
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<td>LDL (mg/dL)</td>
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<td>Serum creatinine (mg/dL)</td>
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<td>SE</td>
<td>N</td>
<td>Mean</td>
<td>SE</td>
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<td>-</td>
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*=p<.05; **=p<.01; ***=p<.001
Exhibit 2-5 (continued)
Recipient Laboratory Values at First Infusion

**HbA1c (%)**

- **Age Group**
  - <12 yrs
  - 12-<18 yrs
  - 18-<35 yrs
  - >=35 yrs

- **Era**
  - 1999-2002
  - 2003-2006
  - 2007-2010
  - 2011-2014
  - 2015-2018

**Basal C-peptide (ng/mL)**

- **Age Group**
  - <12 yrs
  - 12-<18 yrs
  - 18-<35 yrs
  - >=35 yrs

- **Era**
  - 1999-2002
  - 2003-2006
  - 2007-2010
  - 2011-2014
  - 2015-2018

**Fasting blood glucose (mg/dL)**

- **Age Group**
  - <12 yrs
  - 12-<18 yrs
  - 18-<35 yrs
  - >=35 yrs

- **Era**
  - 1999-2002
  - 2003-2006
  - 2007-2010
  - 2011-2014
  - 2015-2018
Exhibit 2-5 (continued)
Recipient Laboratory Values at First Infusion

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Chapter 2
Page 2-51
Recipient Laboratory Values at First Infusion

- **Total bilirubin (mg/dL)**
  - Age Group: <12 yrs, 12-<18 yrs, 18-<35 yrs, >=35 yrs

- **Total cholesterol (mg/dL)**
  - Age Group: <12 yrs, 12-<18 yrs, 18-<35 yrs, >=35 yrs

- **HDL (mg/dL)**
  - Age Group: <12 yrs, 12-<18 yrs, 18-<35 yrs, >=35 yrs
Exhibit 2-5 (continued)
Recipient Laboratory Values at First Infusion

**LDL (mg/dL)**
- Age Group: <12 yrs, 12-<18 yrs, 18-<35 yrs, >=35 yrs

**Triglycerides (mg/dL)**
- Age Group: <12 yrs, 12-<18 yrs, 18-<35 yrs, >=35 yrs

**Serum creatinine (mg/dL)**
- Age Group: <12 yrs, 12-<18 yrs, 18-<35 yrs, >=35 yrs
Chapter 3
Islet Processing Characteristics
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- Exhibit 3-4 Correlation of Islet Characteristics with Recipient, Recovery, and Processing Characteristics ........................................................................................................................ 7
Introduction

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

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

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

The only remarkable correlations between recipient/donor characteristics and islet product characteristics are (Exhibit 3-4):
- Negative correlation between recipient/donor age and total particle count
- Positive correlation between recipient/donor BMI and total IEQs
- Negative correlation between cold ischemia time and both total particle count and total IEQs
Exhibit 3-1
Islet Processing Summary

Data on procurement team and islet processing center relatedness to the transplant center, islet culturing, gradient type, preservation solution, islet purification, density gradient, and microbiology testing are too sparsely reported to allow any meaningful results tabulation. Exhibit 3-1 is intentionally omitted.
### Exhibit 3-2

**Cold ischemia information**

<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
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<td>Mean</td>
<td>SD</td>
<td>N</td>
<td>Mean</td>
<td>SD</td>
<td>N</td>
<td>Mean</td>
<td>SD</td>
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<td>Time from admission to pancreatotomy (hrs)</td>
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<td>Time from pancreatotomy to transplant (hrs)</td>
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<td>Time from cross clamp to pancreas recovery (hrs)</td>
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<td>0</td>
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<td>-</td>
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<tr>
<td>Duration of cold ischemia (hrs)</td>
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<td>0.6</td>
<td>0.1</td>
<td>9</td>
<td>1.4</td>
<td>0.5</td>
<td>35</td>
<td>2.3</td>
<td>2.1</td>
<td>113</td>
<td>1.8</td>
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<td>Culture time (hrs)</td>
<td>0</td>
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<td>-</td>
<td></td>
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### Exhibit 3-3
Islet Product Characteristics (Cumulative through all infusions per recipient)

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<thead>
<tr>
<th></th>
<th>Infusions</th>
<th>&lt;12 yrs</th>
<th>12-&lt;18 yrs</th>
<th>18-&lt;35 yrs</th>
<th>&gt;=35 yrs</th>
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<td></td>
<td>N</td>
<td>Mean</td>
<td>SE</td>
<td>N</td>
<td>Mean</td>
<td>SE</td>
</tr>
<tr>
<td>Total cell volume</td>
<td>4</td>
<td>4.8</td>
<td>2.2</td>
<td>17</td>
<td>6.8</td>
<td>1.5</td>
</tr>
<tr>
<td>Total islet particles (final preparation, 1000s)</td>
<td>8</td>
<td>268.3</td>
<td>49.9</td>
<td>23</td>
<td>274.2</td>
<td>34.3</td>
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<tr>
<td>Embedded islets (%)</td>
<td>0</td>
<td>-</td>
<td>-</td>
<td>1</td>
<td>5.0</td>
<td>-</td>
</tr>
<tr>
<td>Islet equivalents (1000s)</td>
<td>9</td>
<td>196.2</td>
<td>40.0</td>
<td>21</td>
<td>201.9</td>
<td>32.7</td>
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<tr>
<td>Islet equivalents(1000s)/kg recipient</td>
<td>3</td>
<td>7.0</td>
<td>0.7</td>
<td>2</td>
<td>3.0</td>
<td>1.9</td>
</tr>
<tr>
<td>Total Endotoxin units</td>
<td>3</td>
<td>135.3</td>
<td>48.6</td>
<td>2</td>
<td>185.7</td>
<td>174.3</td>
</tr>
<tr>
<td>Endotoxin units/kg recipient weight</td>
<td>3</td>
<td>3.7</td>
<td>1.7</td>
<td>2</td>
<td>3.6</td>
<td>3.2</td>
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<tr>
<td>Islet viability</td>
<td>3</td>
<td>90.0</td>
<td>2.9</td>
<td>4</td>
<td>95.8</td>
<td>0.9</td>
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<tr>
<td>Purity</td>
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<td>0.6</td>
<td>1</td>
<td>8.0</td>
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### Exhibit 3-4
Correlation of Islet Characteristics with Recipient, Recovery, and Processing Characteristics

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<tr>
<th></th>
<th>Packed cell volume</th>
<th>Total particle count</th>
<th>Trapped islets</th>
<th>Total IEQs infused</th>
<th>IEQs/kg donor</th>
<th>Total beta cells</th>
<th>Beta cells/kg donor</th>
<th>Insulin content</th>
<th>Total endotoxin</th>
<th>Endotoxin/kg donor</th>
<th>Stimulation index</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mean recipient age (yrs)</strong></td>
<td>0.05430 0.3870 256</td>
<td>-0.13269 0.0031 494</td>
<td>-0.11533 0.2437 104</td>
<td>-0.04343 0.3428 479</td>
<td>-0.15288 0.2744 53</td>
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<td>0</td>
<td>-0.03617 0.6864 127</td>
<td>-0.08101 0.3811 119</td>
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</tr>
<tr>
<td><strong>Recipient Weight (kg)</strong></td>
<td>-0.07443 0.5589 64</td>
<td>-0.06849 0.3304 204</td>
<td>-0.03611 0.7255 97</td>
<td>0.0020 0.3177 189</td>
<td>-0.13991 0.3177 53</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0.17673 0.0545 119</td>
<td>-0.00806 0.9307 119</td>
<td></td>
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<tr>
<td><strong>Recipient height</strong></td>
<td>-0.14535 0.2518 64</td>
<td>-0.06347 0.3756 197</td>
<td>-0.08042 0.4312 98</td>
<td>-0.02241 0.7596 189</td>
<td>-0.21214 0.1477 48</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0.03423 0.7129 118</td>
<td>-0.06618 0.4861 113</td>
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<tr>
<td><strong>Recipient Body Mass Index (kg/m2)</strong></td>
<td>-0.10532 0.4232 60</td>
<td>0.10935 0.1342 189</td>
<td>-0.01489 0.8873 93</td>
<td>0.26385 0.0003 181</td>
<td>-0.11377 0.4413 48</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0.19246 0.0411 113</td>
<td>0.04363 0.6463 113</td>
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<tr>
<td><strong>Hours from admission to pancreatectomy</strong></td>
<td>0.02055 0.9258 23</td>
<td>-0.11576 0.4654 42</td>
<td>-0.40272 0.0783 20</td>
<td>-0.24392 0.1557 38</td>
<td>-0.66948 0.7796 21</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>-0.09516 0.6509 25</td>
<td>-0.15667 0.4862 22</td>
<td></td>
</tr>
<tr>
<td><strong>Hours from pancreatectomy to transplant</strong></td>
<td>-0.20781 0.2705 30</td>
<td>-0.10535 0.4761 48</td>
<td>-0.34642 0.0973 24</td>
<td>0.12173 0.4326 44</td>
<td>0.05347 0.7911 27</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>-0.34306 0.0588 31</td>
<td>-0.26637 0.1706 28</td>
<td></td>
</tr>
<tr>
<td><strong>Cold ischemic time (hrs)</strong></td>
<td>0.21030 0.2253 35</td>
<td>-0.24890 0.0015 160</td>
<td>-0.15046 0.1569 90</td>
<td>-0.30675 0.0002 145</td>
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<td>0</td>
<td>0.10344 0.2822 110</td>
<td>0.19443 0.0491 103</td>
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Chapter 4
Autologous Islet Recipient Medications
This Chapter is intentionally left blank
Chapter 5
Graft Function
<table>
<thead>
<tr>
<th>Exhibit</th>
<th>Description</th>
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<tr>
<td>5-1A</td>
<td>First Achievement of Insulin Independence (Intentionally omitted)</td>
</tr>
<tr>
<td>5-2A</td>
<td>Prevalence of Insulin Independence Post Last Infusion by Age Group</td>
</tr>
<tr>
<td>5-2B</td>
<td>Univariate Effects of Individual Variables (p&lt;0.01) on Prevalence of Insulin Independence Post Last Infusion among Recipients 35 and over</td>
</tr>
<tr>
<td>5-2C</td>
<td>Univariate Effects of Individual Variables (p&lt;0.01) on Prevalence of Insulin Independence Post Last Infusion among Recipients 18 to 35</td>
</tr>
<tr>
<td>5-2D</td>
<td>Univariate Effects of Individual Variables (p&lt;0.01) on Prevalence of Insulin Independence Post Last Infusion among Recipients 12 to 18</td>
</tr>
<tr>
<td>5-2E</td>
<td>Univariate Effects of Individual Variables (p&lt;0.01) on Prevalence of Insulin Independence Post Last Infusion among Recipients 12 and under</td>
</tr>
<tr>
<td>5-3</td>
<td>Retention of C-peptide ≥0.3 ng/mL Post Last Infusion</td>
</tr>
<tr>
<td>5-4A</td>
<td>Prevalence of C-peptide ≥0.3 ng/mL Post Last Infusion by Age Group (p=NS)</td>
</tr>
<tr>
<td>5-4B</td>
<td>Univariate Effects of Individual Variables (p&lt;0.01) on Prevalence of C-peptide ≥0.3 ng/mL Post Last Infusion among Recipients 35 and over</td>
</tr>
<tr>
<td>5-4C</td>
<td>Univariate Effects of Individual Variables (p&lt;0.01) on Prevalence of C-peptide ≥0.3 ng/mL Post Last Infusion among Recipients 18 to 35</td>
</tr>
<tr>
<td>5-4D</td>
<td>Univariate Effects of Individual Variables (p&lt;0.01) on Prevalence of C-peptide ≥0.3 ng/mL Post Last Infusion among Recipients 12 to 18</td>
</tr>
<tr>
<td>5-4E</td>
<td>Univariate Effects of Individual Variables (p&lt;0.01) on Prevalence of C-peptide ≥0.3 ng/mL Post Last Infusion among Recipients 12 and under</td>
</tr>
<tr>
<td>5-5A</td>
<td>Prevalence of Fasting Blood Glucose 60-140 mg/mL Post Last Infusion by Age Group</td>
</tr>
<tr>
<td>5-5B</td>
<td>Univariate Effects of Individual Variables (p&lt;0.01) on Prevalence of Fasting Blood Glucose 60-140 mg/mL Post Last Infusion among Recipients 35 and over</td>
</tr>
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<td>5-5C</td>
<td>Univariate Effects of Individual Variables (p&lt;0.01) on Prevalence of Fasting Blood Glucose 60-140 mg/mL Post Last Infusion among Recipients 18 to 35</td>
</tr>
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<td>5-5D</td>
<td>Univariate Effects of Individual Variables (p&lt;0.01) on Prevalence of Fasting Blood Glucose 60-140 mg/mL Post Last Infusion among Recipients 12 to 18</td>
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<tr>
<td>5-5E</td>
<td>Univariate Effects of Individual Variables (p&lt;0.01) on Fasting Blood Glucose 60-140 mg/mL Post Last Infusion among Recipients 12 and under</td>
</tr>
<tr>
<td>5-6A</td>
<td>Prevalence of HbA1c&lt;7.0% Post Last Infusion by Age Group (p&lt;0.0001)</td>
</tr>
<tr>
<td>5-6B</td>
<td>Univariate Effects of Individual Variables (p&lt;0.01) on Prevalence of HbA1c&lt;7.0% Post Last Infusion among Recipients 35 and over</td>
</tr>
<tr>
<td>5-6C</td>
<td>Univariate Effects of Individual Variables (p&lt;0.01) on Prevalence of HbA1c&lt;7.0% Post Last Infusion among Recipients 18 to 35</td>
</tr>
<tr>
<td>5-6D</td>
<td>Univariate Effects of Individual Variables (p&lt;0.01) on Prevalence of HbA1c&lt;7.0% Post Last Infusion among Recipients 12 to 18</td>
</tr>
</tbody>
</table>
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Exhibit 5-10 Fasting C-peptide (ng/mL) Post Last Infusion.......................................................22

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Exhibit 5-12 Fasting Blood Glucose (mg/dL) Post Last Infusion ..................................................25
Introduction

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

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

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

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

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

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

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

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

**Recipients 18-35 years old**

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

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

**Recipients <18 years old**

These groups had too small sample size to uncover any factors associated with improved levels of insulin independence following transplantation (Exhibits 5-2C and 5-2D).
Age was not a significant factor of C-peptide≥0.3 ng/mL prevalence over five years post auto-ITx (Exhibit 5-4A). For the ≥35-year-old patients, largely the same variables that influenced insulin independence rates also influenced rates of C-peptide≥0.3 mg/dL (Exhibit 5-4B). Lower HbA1c at baseline, higher particles at count, >300K IEQs infused, no prior treatment ERCP, no prior plastic stent, no prior other medical procedure, indication other than chronic pancreatitis, partial pancreatectomy all exhibited improved retention of C-peptide>-0.3 ng/mL over 5 years. The differences by era are not readily explained.

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

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

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

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

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

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

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

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

Fasting blood sugar as a continuous variable varied substantially by age with worse outcomes in those aged ≥35, was improved with ≥325K total IEQs infused, and varied by pancreatitis etiology.
For most of the primary metabolic endpoints, data interpretation is limited by the ~50% levels of missing data, for much follow-up including insulin independence and insulin use. All indications are that the data are missing at random, i.e., not selectively for insulin use or independence. From available data, **Insulin Dose** (Exh 5-9) when reported did not vary by age, era, total IEQs infused, or pancreatitis etiology. **Fasting C-peptide** boxplots (Exhibit 5-10) decreased over time after TPIAT and differed by era and pancreatitis etiology. **HbA1c boxplots** (Exhibit 5-11) varied by era, age group, total IEQs (higher IEQs were better), and pancreatitis etiology. **Fasting plasma glucose** (FPG) as a continuous variable varied substantially by age, total IEQs infused (≥325K were better), and varied by pancreatitis etiology. HbA1c and FPG were worse in those ≥35 years of age, as was HbA1c in those 12 - <18 years of age. HbA1c and FPG patterns differed by etiology of disease, which appears in part driven by worse glycemic control in Auto-Itx for alcoholic pancreatitis. Alcoholic pancreatitis has previously been associated in the literature with lower islet mass isolated for transplant and lower rates of insulin independence.
Exhibit 5-1A
First Achievement of Insulin Independence
This exhibit is intentionally omitted

Exhibit 5-2A
Prevalence of Insulin Independence Post Last Infusion by Age Group (p=NS)
Exhibit 5-2B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Insulin Independence Post Last Infusion among Recipients 35 and over

A. Baseline HDL (p=0.0044)

B. Baseline triglycerides (p=0.0022)

C. Diagnostic ERCP (p=0.0035)

D. Treatment ERCP (p=0.0055)

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

A. IEQs (1000s, particle count) (p<0.0001)

B. IEQs infused (1000s) (p=0.0049)

C. Pancreatectomy type (p=0.0001)

D. Diagnostic ERCP (p=0.0085)

Exhibit 5-2D
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Insulin Independence Post Last Infusion among Recipients 12 to 18

None

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

None
Exhibit 5-3
Retention of C-peptide ≥0.3 ng/mL Post Last Infusion

| Exhibit is intentionally omitted |
Exhibit 5-4A
Prevalence of C-peptide ≥0.3 ng/mL Post Last Infusion by Age Group (p=NS)

Exhibit 5-4B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of C-peptide ≥0.3 ng/mL Post Last Infusion among Recipients 35 and over

A. Baseline HbA1c (p=0.0004)

B. IEQs (1000s, particle count) (p=0.0001)

C. IEQs infused (p=0.0047)

D. IEQs infused/kg weight (p=0.0083)
Exhibit 5-4B (continued)
Univariate Effects of Individual Variables (p<0.01) on Prevalence of C-peptide ≥0.3 ng/mL
Post Last Infusion among Recipients 35 and over

E. Treatment ERCP (p=0.0050)

F. Plastic Stent (p=0.01)

G. Other prior medical procedure (p=0.0080)

H. Indication: Chronic pancreatitis (p=0.0050)

Exhibit 5-4C
Univariate Effects of Individual Variables (p<0.01) on Prevalence of C-peptide ≥0.3 ng/mL
Post Last Infusion among Recipients 18 to 35

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

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

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

Exhibit 5-4D
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 5-4E
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 5-5A
Prevalence of Fasting Blood Glucose 60-140 mg/mL Post Last Infusion by Age Group
(p=0.0006)

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

A. Baseline fasting C-peptide (p<0.0001)

B. Baseline CKD-GFR (p<0.0001)

D. Pancreatectomy type (p<0.0001)
### Exhibit 5-5C
Univariate Effects of Individual Variables (p<0.01) on Prevalence of Fasting Blood Glucose 60-140 mg/mL Post Last Infusion among Recipients 18 to 35

| None |

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

| None |

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

Exhibit 5-6B
Univariate Effects of Individual Variables (p<0.01) on Prevalence of HbA1c<7.0% Post Last Infusion among Recipients 35 and over

C. Indication: Other (p=0.0059)
D. Pancreatitis etiology (p<0.0001)

Exhibit 5-6B (continued)

Univariate Effects of Individual Variables (p<0.01) on Prevalence of HbA1c<7.0% Post Last Infusion among Recipients 35 and over
Exhibit 5-6C
Univariate Effects of Individual Variables (p<0.01) on Prevalence of HbA1c<7.0% Post Last Infusion among Recipients 18 to 35

None

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

None

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

None
Exhibit 5-7
Prevalence of Absence of Severe Hypoglycemic Events Post Last Infusion by Age Group
(p<0.0001)

Children 12 and under

Adolescents 12 to 18

Adults 18 to 35

Adults 35 and over
Exhibit 5-8
Intentionally omitted
Exhibit 5-9
Insulin Dose (U/day) Post Last Infusion

Overall*

*No factors significant at p<0.01
Exhibit 5-10
Fasting C-peptide (ng/mL) Post Last Infusion

Overall

Era (p<0.0001)

Pancreatitis etiology (p<0.0001)
Exhibit 5-11
HbA1c (%) Post Last Infusion

Overall

Age (p<0.0001)

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

Pancreatitis etiology (p<0.0001)
Exhibit 5-12
Fasting Blood Glucose (mg/dL) Post Last Infusion

Overall

Age (p=0.001)

Pancreatitis etiology (p<0.0001)
Appendix A: Autologous Islet Transplant Center Contributors
(Centers and Staff are listed in alphabetical order)
(*=inactive sites; #=data not included in 1st Annual Autograft Report)

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(*=inactive sites; #=data not included in 1st Annual Autograft Report)

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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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