Hematopoietic Stem Cell Transplant in Puerto Rico

Alexis M. Cruz Chacón, MD FACP
Hematology and Medical Oncology
Blood and Marrow Transplantation
How a HSCT Works?

Hematopoietic Stem Cell Transplant:
- HSCs: Rescue or Replace BM
- T cells against:
  1. Leukemia = GVL
  2. Host tissues = GVHD

Radio-chemotherapy:
- Debulk malignancy (Auto/Allo)
- Suppress host immunity (Allo)

GVHD, GVL, Infection
Why to perform a HSCT?

**AUTOLOGOUS HSCT**

Allow administration of high dose anti-neoplastic therapy, avoiding prolonged or irreversible myelosupression through administration of rescue HSCs from patient.

**ALLOGENEIC HSCT**

Replace a hematopoietic system that is deficient, insufficient or neoplastic for a normal one from a healthy donor.
HSC Collection

DONOR (HLA compatible)

HSC Processing

HSC Infusion

ALLOGENEIC HSCT

Immunosuppressive Therapy

Conditioning Therapy

RECIPIENT (patient)

AUTOLOGOUS HSCT

HSC Collection

HSC Processing

Cryopreservation

HSC Infusion
Number of Autologous HCTs in the U.S. by Selected Disease

- MM/PCDs
- NHL/HL

Number of Transplants

Number of HCTs by Indications in the U.S., Pediatric, 2021

- **Allogeneic**
- **Autologous**

### Number of Transplants

- **Other Non-Malignant Diseases**
- **Other Malignancy**
- **ALL**
- **AML**
- **Aplastic Anemia**
- **HL**
- **MDS/MPN**
- **CML**
- **NHL**
- **CLL**

### Abbreviations
- ALL: Acute Lymphoblastic Leukemia
- AML: Acute Myeloid Leukemia
- HL: Hodgkin Lymphoma
- MDS: Myelodysplastic Syndromes
- MPN: Myeloproliferative Neoplasms
- CML: Chronic Myeloid Leukemia
- NHL: Non-Hodgkin Lymphoma
- CLL: Chronic Lymphocytic Leukemia

Non-malignant disease excludes Aplastic Anemia.
Pediatric: <18 years
Number of HCTs by Indications in the U.S., Adult, 2021

Abbreviations –
PCDs: Plasma Cell Disorders;
AML: Acute Myeloid Leukemia;
NHL: Non-Hodgkin Lymphoma;
MDS: Myelodysplastic Syndromes;
MPN: Myeloproliferative Neoplasms;
ALL: Acute Lymphoblastic Leukemia;
HL: Hodgkin Lymphoma;
CML: Chronic Myeloid Leukemia;
CLL: Chronic Lymphocytic Leukemia.
Non-malignant disease excludes Aplastic Anemia. Adult ≥18 years.
Cancer Incidence in Puerto Rico

- According to the Puerto Rico Cancer Registry, during the 2016-2020 period, 71,769 persons were diagnosed with cancer in Puerto Rico.
- NHL comprises 3.9% of cancer cases in PR for males and 3.9% for females.
- Leukemia comprises 2.8% of cancer cases in PR for males and 2.4% for females.

<table>
<thead>
<tr>
<th>Cancer Site</th>
<th>% Male (N = 37,548)</th>
<th>% Female (N = 34,221)</th>
<th>AAPC&lt;sup&gt;2000-2019&lt;/sup&gt;</th>
<th>AAPC&lt;sup&gt;2000-2019&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prostate</td>
<td>38.3</td>
<td>30.5</td>
<td>1.7*</td>
<td>1.7*</td>
</tr>
<tr>
<td>Colon and rectum</td>
<td>11.5</td>
<td>10.5</td>
<td>0.2</td>
<td>-0.1</td>
</tr>
<tr>
<td>Lung and bronchus</td>
<td>5.4</td>
<td>4.0</td>
<td>-1.0*</td>
<td>0.4</td>
</tr>
<tr>
<td>Urinary bladder</td>
<td>4.4</td>
<td>9.5</td>
<td>0.1</td>
<td>9.0*</td>
</tr>
<tr>
<td>Oral cavity and pharynx</td>
<td>3.5</td>
<td>4.0</td>
<td>-0.7*</td>
<td>0.4</td>
</tr>
<tr>
<td>Liver and bile duct</td>
<td>3.5</td>
<td>2.5</td>
<td>1.9*</td>
<td>3.1*</td>
</tr>
<tr>
<td>Kidney and renal pelvis</td>
<td>3.1</td>
<td>2.4</td>
<td>4.3*</td>
<td>2.7*</td>
</tr>
<tr>
<td>Leukemia</td>
<td>2.8</td>
<td>2.4</td>
<td>2.2*</td>
<td>2.7*</td>
</tr>
<tr>
<td>Pancreas</td>
<td>2.6</td>
<td>2.3</td>
<td>2.2*</td>
<td>0.8*</td>
</tr>
<tr>
<td>Other sites</td>
<td>21.1</td>
<td>21.9</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* AAPC indicates annual percentage change.
**BMT related cancer cases in Puerto Rico**

- Estimated Cases for year 2016-2020 derived from incidence rates per 100,000 persons (published by the PR Cancer Registry).
- NHL had the largest number of new BMT related cancer cases.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Estimated Cases</th>
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</thead>
<tbody>
<tr>
<td>AML</td>
<td>563</td>
</tr>
<tr>
<td>ALL</td>
<td>209</td>
</tr>
<tr>
<td>NHL</td>
<td>2880</td>
</tr>
<tr>
<td>Hodgkin’s lymphoma</td>
<td>423</td>
</tr>
<tr>
<td>Multiple Myeloma</td>
<td>1351</td>
</tr>
</tbody>
</table>

**TOTAL CASES: 5426**
Pediatric BMT programs in Puerto Rico

- Two main Pediatric BMT programs:
  - San Jorge Children’s Hospital (autologous and allogeneic, Closed in 2019)
  - University Pediatric Hospital in Centro Medico (autologous and allogeneic)

- Data from both centers collected from 1994 through December 2009:
  - **97** transplants performed to **87** children and young adults
  - **55** males and **32** females, aged between **12** months and **38** years
  - Source of HSCs:
    - **52** autologous (5 BM, 47 PBSC)
    - **45** allogeneic (23 MRD BM, 18 MRD PBSC, 1 syngeneic PBSC, 4 Haploidentical BM)
  - Diagnosis: Acute leukemia, chronic leukemia, MDS, aplastic anemia, histiocytosis, neuroblastoma, lymphomas, PNET, Wilms tumor, and desmoplastic round cell tumor

- HIMA-San Pablo Hospital – Caguas, PR
  - Dr. John Guerra (4 Autologous, 1 Allogeneic)
Adult BMT programs in Puerto Rico

- **University District Hospital - Centro Medico**
  - Founded in **1997** by Dr. Justiniano Castro
  - Autologous HCT
  - Approximately 25 transplants per year

- **HIMA-San Pablo Hospital – Caguas, PR**
  - Founded in **2010** by Dr. Norma Salgado Vila
  - Autologous HCT
  - Approximately 35 transplants per year (Total 453)

- **Hospital Español Auxilio Mutuo – San Juan, PR**
  - Founded in **2015** by Dr. Alexis M. Cruz Chacón
  - Autologous HCT
Hematopoietic Stem Cell Collection and Processing

- HSC collection, processing, cryopreservation and administration in Puerto Rico performed by the American Red Cross (ARC).

- ARC is the only provider of these services for all BMT Programs in Puerto Rico.
HSCs from Puerto Rico Donors saved lives around the World

• Approximately 100 matched unrelated donors collected for NMPD during the year period from 2011 to 2020.
The Road to Adult Allogeneic HCT for Puerto Rico

- Adult BMT Programs in Puerto Rico only performed Autologous HCT
  - Around 40 cases per year on each adult program
  - Adult patients in need for Allogeneic HCT must travel to USA

- In 2011 Moffitt Cancer Center BMT program (Tampa, FL) established a monthly clinic in Bayamon, Puerto Rico for initial evaluation of patients with indications for BMT (allogeneic and autologous)
  - Dr. Melissa Alsina and Dr. Leonel Ochoa Bayona
  - Patients still needed to travel to US to receive Allogeneic HCT

**Allogeneic HCT was still a NECESSITY for Adult patients in PR**
A good reason to have Allogeneic HCT done locally in PR

1.6 million patients
NO COVERAGE FOR BMT

MAXIMUM APPROVED FUNDS PER CASE
$340,000.00

MINIMAL COST OF MUD HSCT IN USA
$450,000.00
2014: A Door Opened
One of Puerto Rico’s biggest Hospitals.

Successful solid organ transplant program.

Accredited Histocompatibility and Immunogenic Lab.

Medical faculty with over 700 specialists and subspecialists.

Wide range of diagnostic and treatment services with multiple specialized centers and units in the same place.

Significant population of patients with indications for BMT referred to Auxilio Cancer Center.

Optimal Institution to start an Allogeneic BMT Program
Collaboration with Moffitt Cancer Center

• Counseling for design of BMT program with the standard of care.
• Education and training of BMT unit nurse manager and BMT coordinator.
• Assistance and counseling for development and implementation of BMT specific nursing educational curriculum and clinical competencies in our institution.
• Consult of difficult or challenging cases with team of experienced and renowned BMT physicians.
AUXILIO MUTUO BMT PROGRAM
OUR FIRST STEPS

September 2014
Construction of BMT Unit Started

October 2014
Training of Manager and Coordinator at Moffitt

March 2015
Opening of BMT Unit
Started evaluation of BMT Candidates at Clinic

May 2015
First Autologous HCT
AUXILIO MUTUO BMT PROGRAM
OUR CRAZY DREAM CAME TRUE

February 2017
First Two MRD Allogeneic HCTs

2/7/17

2/16/17

March 2018
First Haploidentical HCT
First BM Harvest

3/23/18
AUXILIO MUTUO BMT PROGRAM
JOINING FORCES TO BUILD A SOLID TEAM AND PREPARE FOR THE FUTURE

August 2019
Dr. Joel López
Multiple Myeloma Clinic

June 2020
BMT Ambulatory Clinic Facility Inaugurated

August 2020
Dr. Carlos Perez
BMT Infectious Diseases

March–May 2020
COVID-19 Pandemic
15 Autologous HCT
3 Allogeneic HCT

July 2020
Dr. Cristian Rodríguez
BMT-CI Specialist CART

October 2023
Dr. Carlos Bachier
BMT-CI Specialist CART, Research
TILL YEAR 2023

478 TRANSPLANTS
359 AUTOLOGOUS
119 ALLOGENEIC
Total HCTs by Sex, BMT-HAM 2015 – 2023

AUTOLOGOUS

ALLOGENEIC

Female Male

56% 44%

46% 54%

Female Males
Total HCTs by Type, BMT-HAM 2015 – 2023

HCTs Total

0 0 10 32 28 31 33 50 52 55 68

Transplant Year

2017 Huracán María

2020 COVID-19

Autologous  Allogeneic
Total Allogeneic HCTs by Donor and Source Type, BMT-HAM 2015 – 2023

**DONOR TYPE**

- HAPLO: 50
- MRD: 1
- MUD: 68

**SOURCE TYPE**

- BM: 113
- Peripheral: 6
Total Allogeneic HCTs by Type, BMT-HAM 2015 – 2023

<table>
<thead>
<tr>
<th>Transplant Year</th>
<th>MRD</th>
<th>Haplo</th>
<th>MUD</th>
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<tbody>
<tr>
<td>2017</td>
<td>3</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>2018</td>
<td>4</td>
<td>11</td>
<td>0</td>
</tr>
<tr>
<td>2019</td>
<td>8</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>2020</td>
<td>10</td>
<td>6</td>
<td>0</td>
</tr>
<tr>
<td>2021</td>
<td>9</td>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td>2022</td>
<td>16</td>
<td>12</td>
<td>0</td>
</tr>
<tr>
<td>2023</td>
<td>21</td>
<td></td>
<td>0</td>
</tr>
</tbody>
</table>
Total HCTs by Age Group, BMT-HAM 2015 – 2023

**AUTOLOGOUS**
- 0-17 yrs: 0%
- 18-39 yrs: 17%
- 40-64 yrs: 27%
- 65+ yrs: 56%

**ALLOGENEIC**
- 0-17 yrs: 46%
- 18-39 yrs: 45%
- 40-64 yrs: 8%
- 65+ yrs: 1%
Total Autologous HCTs by Age Group and Condition, BMT-HAM 2015 – 2023

N = 478 HCT’s
Total Allogeneic HCTs by Age Group and Condition, BMT-HAM 2015 – 2023

<table>
<thead>
<tr>
<th>Age Group</th>
<th>ALL</th>
<th>AML</th>
<th>CML</th>
<th>CMML</th>
<th>BMF</th>
<th>HL</th>
<th>MDS</th>
<th>MF</th>
<th>NHL</th>
<th>SAA</th>
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</thead>
<tbody>
<tr>
<td>0-17 yrs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18-39 yrs</td>
<td>10</td>
<td>30</td>
<td>20</td>
<td>5</td>
<td>10</td>
<td>5</td>
<td>10</td>
<td>5</td>
<td>10</td>
<td>5</td>
</tr>
<tr>
<td>40-64 yrs</td>
<td>20</td>
<td>40</td>
<td>30</td>
<td>6</td>
<td>20</td>
<td>10</td>
<td>20</td>
<td>10</td>
<td>20</td>
<td>10</td>
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<tr>
<td>65+ yrs</td>
<td>10</td>
<td>30</td>
<td>20</td>
<td>5</td>
<td>10</td>
<td>5</td>
<td>10</td>
<td>5</td>
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</table>

N = 478 HCT's
## Survival 2021-2022

<table>
<thead>
<tr>
<th></th>
<th>2021 Survival %</th>
<th>2022 Survival %</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>+30 days</td>
<td>+100 days</td>
</tr>
<tr>
<td><strong>Auto HCT</strong></td>
<td>52/52 = 100.0%</td>
<td>52/52 = 100.0%</td>
</tr>
<tr>
<td><strong>Allo HCT</strong></td>
<td>14/17 = 82.3%</td>
<td>13/17 = 76.5%</td>
</tr>
<tr>
<td><strong>Total HCT</strong></td>
<td>66/69 = 95.7%</td>
<td>65/69 = 94.2%</td>
</tr>
</tbody>
</table>
Total Autologous HCTs by Municipality, San Juan P.R. 2015 – 2023
Total Allogeneic HCTs by Municipality, San Juan P.R. 2015 – 2023
Total HCTs by Healthcare Plan, BMT-HAM 2015 – 2023

**AUTOLOGOUS**
- Vital: 31%
- Comercial: 32%
- Medicare: 7%
- Advantage: 2%
- VA: 2%

**ALLOGENEIC**
- Vital: 46%
- Comercial: 36%
- Medicare: 14%
- Advantage: 4%
- VA: 2%
What's Next?

FUTURE AHEAD

Auxilio Trasplante de Médula Osea y Terapia Celular

TCT Oncology
Transplant & Cellular Therapy
2024: Ten Years Later
YES, WE ARE STILL DREAMING
Can we give CAR T cells in PR?

- Multi-disciplinary teams and infrastructures to manage logistics and patient care
- Robust quality processes and infrastructure

- 179 Auto-HCT
- 39 Allo-HCT (17 Haplo-T)
- >60% patients with Government Insurance

Dr. Cristian Rodriguez Arocho
REALITY: The road to CAR T in PR isn’t an easy one.

In 2024: Can we still give CAR T cells in PR? YES!!!
Caminante, son tus huellas
el camino y nada más;
Caminante, no hay camino,
se hace camino al andar.
Al andar se hace el camino,
y al volver la vista atrás
se ve la senda que nunca
se ha de volver a pisar.
Caminante no hay camino
sino estelas en la mar.