The Argentinian Transplantation Registry: A Latin American “Bright Spot”
Disclosures

• I have nothing to disclose
Population: 44 million inhabitants
Surface: 2.791.810 Km²
The country is divided into 24 provinces and Buenos Aires City
INCUCAI, decentralized organism depending on the National Ministry of Health -created by National Law Nº 24.193-, is the national authority that coordinates organ, tissue and cell procurement and transplantation.

Highest Rate of donors: 15.1 PMP (per million population) in 2012

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</tr>
</thead>
<tbody>
<tr>
<td>Heart Donors/ Real Donors (%)</td>
<td>17%</td>
<td>14%</td>
<td>13%</td>
<td>13%</td>
<td>14%</td>
<td>14%</td>
<td>14%</td>
<td>15%</td>
</tr>
<tr>
<td>Donors Rate pmp</td>
<td>12,6</td>
<td>14,3</td>
<td>14,7</td>
<td>15,1</td>
<td>13,5</td>
<td>13,1</td>
<td>13,7</td>
<td>11,9</td>
</tr>
<tr>
<td>Heart Donors Rate pmp</td>
<td>2,1</td>
<td>2,0</td>
<td>1,9</td>
<td>1,9</td>
<td>1,9</td>
<td>1,8</td>
<td>1,9</td>
<td>1,7</td>
</tr>
</tbody>
</table>
SINTRA (National Information System of Procurement and Transplantation)

SINTRA is the online database system that administrates, manages and supervises organ, tissue and cell procurement and transplantation activities in the national field.

A project impelled, coordinated and financed by INCUCAI, that started in 2003 and still continues its development.

Main strategy

To decentralize information management, in order to empower all the actors that take part in the different processes by interacting directly with SINTRA, and to centralize information in a unique database, integrated and consolidated.
Main objectives

APPLY THE REGULATORY FRAMEWORK
To implement all the regulations established by INCUCAI policies through computer based procedures that guarantee their accomplishment.

REGISTRY
To create and keep updated national registries related to procurement and transplant activity, assuring the protection of personal information as is stated by Law of Habeas Data Nº 25.326.

TRACEABILITY
To allow traceability across every process from donor to recipient and vice versa, assuring confidentiality and different access to information.

ASSESSMENT
To provide regional authority, INCUCAI and other health organizations with a tool that enables them to monitor and audit related activities.

MANAGEMENT CONTROL
To provide health authorities and professional community with a tool that enables them to evaluate and analyze different aspects of the procurement and transplant activity, aiming to help in the decision making process concerning health policies or clinical research.

TRANSPARENCY
To offer society a guarantee of transparency of the activity, allowing access and information availability with several levels of complexity, in order to satisfy different requirements.
## MAJOR CONTRIBUTORS TO THE ISHLT TRANSPLANT REGISTRY

<table>
<thead>
<tr>
<th>Organization</th>
<th>Countries</th>
<th>Heart</th>
<th>Lung</th>
</tr>
</thead>
<tbody>
<tr>
<td>L’Agence de la Biomédecine</td>
<td>France</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Australia and New Zealand Cardiothoracic Organ Transplant Registry (ANZCOTR)</td>
<td>Australia</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Eurotransplant (ET)</td>
<td>Austria, Belgium, Croatia, Germany, Netherlands, Slovenia</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Instituto Nacional Central Único Coordinador de Ablación e Implante (INCUCAI)</td>
<td>Argentina</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Organización Nacional de Trasplantes (ONT)</td>
<td>Spain</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Registro Español de Trasplante Cardíaco</td>
<td>Spain</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Scandiatransplant</td>
<td>Denmark, Finland, Norway, Sweden</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>United Kingdom Transplant Services Authority (UKTSSA)</td>
<td>United Kingdom, Ireland</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>United Network for Organ Sharing (UNOS)</td>
<td>United States</td>
<td>x</td>
<td>x</td>
</tr>
</tbody>
</table>

In addition, 84 individual centers from North America, Central/South America, Europe, Asia, Africa and the Middle East have reported at least one transplant since 1995.
BENEFIT!!
Increase in data reporting after agreement!

Heart Transplant:
- 2014: 88%
- 2015: 96%

Lung Transplant:
- 2014: 81%
- 2015: 85%
Argentinian Heart Transplant Registry

• All data provided by INCUCAI
  • Scientific and Technical Director: Liliana Bisigniano, MD

• Unpublished data and statistics:
  • Period 1998-2016
  • Donor Heart Procurement
  • Processes and Outcomes on the Waiting List
  • Adult Heart Transplants:
    • Demographics
    • Survival Analysis
Patients on Heart Transplant Waiting List (Period 1998-2016) n=2546

- New Inclusions on WL
- Prevalents on WL

- Transplanted: 54%
- Death on WL: 28%
- Drop Out: 13%
- On WL: 5%

- Urgency: 17%
- Elective: 49%
- Emergency: 34%
Overall Number of Heart Transplants (n=1674) By Year of Transplant: 1998-2016
Overall Heart Transplant Recipients (n=1674)
Recipient Age Distribution by Groups (1998-2016)

Pediatric: 9.1%
Adult Heart Transplants (n=1435)
Donor Age By Year of Transplant: 1998-2016

Median Donor Age: 27.3 years (IC 95% 26.4 to 28.3)

Donors: Cause of Death
- Stroke, 32%
- Head Trauma, 63%
- Others, 5%
Adult Heart Transplant Recipients (n=1435)
Time on Waiting List to Transplant
(Period 1998-2016)

<table>
<thead>
<tr>
<th>CLINICAL STATUS</th>
<th>ELECTIVE</th>
<th>URGENCY</th>
<th>EMERGENCY</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>421</td>
<td>470</td>
<td>544</td>
</tr>
<tr>
<td>Median (Days)</td>
<td>201</td>
<td>47</td>
<td>18</td>
</tr>
<tr>
<td>95% CI</td>
<td>168-234</td>
<td>34-55</td>
<td>15-22</td>
</tr>
</tbody>
</table>

Median (95% CI) 51 (47-58)
Adult Heart Transplants (n=1435) Kaplan-Meier Survival Curve (Transplants: 1998-2016)

Follow-up | Survival
---|---
Argentina | ISHLT
1 Month | 80% | 88%
1 Year | 72% | 81%
3 Years | 64% | 77%
5 Years | 58% | 68%
10 Years | 44% | 54%

Median Survival: 8.43 years

Median survival = 10.7
Adult Heart Transplants (n=1435)
Kaplan-Meier Survival Curve: Conditional to 1st Year Survival
(Transplants: 1998-2016)

Median Conditional Survival: 12.7 years

JHLT. 2016 Oct; 35(10): 1149-1205

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Adult Heart Transplants (n=1435)
Kaplan-Meier Survival by Clinical Status
(Transplants: 1998-2016)

<table>
<thead>
<tr>
<th>Clinical Status</th>
<th>Median Survival</th>
<th>1 year Survival</th>
<th>5 years Survival</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elective</td>
<td>7.6</td>
<td>69%</td>
<td>55%</td>
</tr>
<tr>
<td>Emergency</td>
<td>10.0</td>
<td>73%</td>
<td>63%</td>
</tr>
<tr>
<td>Urgency</td>
<td>6.9</td>
<td>75%</td>
<td>58%</td>
</tr>
</tbody>
</table>

Kaplan-Meier Survival by Clinical Status (Transplants: 1998-2016)
Adult Heart Transplants (n=1435)
Kaplan-Meier Survival by Recipient Age
(Transplants: 1998-2016)

Recipendnt Age
- < 60 years
- > 60 years

P < 0.0001

Patients at Risk
- Group: < 60 years
- Group: > 60 years
  - Years: 15, Patients: 285, 156, 140, 121, 110, 84, 69, 62, 46, 33, 21, 15, 10, 3, 3, 3

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### Number of Adult Heart Transplants By Center Volume Between 1998 and 2016

<table>
<thead>
<tr>
<th>CENTER</th>
<th>% of Tx</th>
</tr>
</thead>
<tbody>
<tr>
<td>FUNDACION FAVALORO</td>
<td>26%</td>
</tr>
<tr>
<td>HOSPITAL ITALIANO DE BUENOS AIRES</td>
<td>14%</td>
</tr>
<tr>
<td>HAREFIELD S.A. - HOSPITAL ITALIANO DE MENDOZA</td>
<td>14%</td>
</tr>
<tr>
<td>HOSPITAL GENERAL DE AGUDOS DR COSME ARGERICH</td>
<td>8%</td>
</tr>
<tr>
<td>CENTRO DE TRASPLANTE CARDIACO HOSPITAL PRIVADO CORDOBA</td>
<td>5%</td>
</tr>
<tr>
<td>CENTRO DE TRASPLANTE CARDIACO HOSPITAL ITALIANO CORDOBA</td>
<td>4%</td>
</tr>
<tr>
<td>INSTITUTO CARDIOVASCULAR DE BUENOS AIRES</td>
<td>3%</td>
</tr>
<tr>
<td>SANATORIO DE LA TRINIDAD MITRE</td>
<td>2%</td>
</tr>
<tr>
<td>SANATORIO PARQUE</td>
<td>2%</td>
</tr>
<tr>
<td>CENTRO DE TRASPLANTE CARDIACO DEL SANATORIO ALLENDE</td>
<td>2%</td>
</tr>
<tr>
<td>SANATORIO SANTA ISABEL</td>
<td>2%</td>
</tr>
</tbody>
</table>

![Graph showing the number of heart transplants by center volume between 1998 and 2016.](image-url)
Adult Heart Transplants (n=1435)
Kaplan-Meier Survival by Center Volume
(Transplants: 1998-2016)

COVARIABLE | P   | HR   | 95% CI of HR
REFERENCE: CENTER VOLUME >36TX
Tx (1998-2016): 12 to 36 <0.0001 1.91 1.58 – 2.30
Tx (1998-2016): < 12 0.0003 2.01 1.37 – 2.93

Heart Tx: 1998-2016
- > 36 Tx
- 12 to 36 Tx
- < 12 Tx

Patients at Risk
Group: > 36 Transplants
970 710
Group: 12 to 36 Transplants
600 536 464 402 335 298 249 196 147 108 78 50 37 26
Group: > 12 Transplants
44 25 15 10 6 4 3 3 2 1 1 1 1 0 0

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Conclusions I:

SINTRA is helpful:

- Control and monitoring activities in INCUCAI and in the regional procurement and transplantation organizations
- Allow management control, identify and detect deviations from the standard of care, apply corrections.
- Perform scientific analysis and clinical research
- Accomplish traceability in different processes
- Guarantee the transparency of the activity
Conclusions II:

Heart Transplant in Argentina

✓ High mortality on WL (28%), specially in elective patients
✓ The number of Tx is increasing (but not enough)
✓ The rate of heart donors is low (mostly young donors)
✓ Majority of Transplants performed on sickest patients (Emergency/Urgency)
✓ Lack of long term VAD as BTT
✓ High early mortality post transplantation (Emergency status, Age > 60 years, Low volume center)
✓ Long term survival is similar to the ISHLT Registry
Thank You