Committee on Issues in Organ Donor Intervention Research

Presented by:
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U.S. National Trends in Organ Donation
Living vs. Deceased Organ Donors
1995 – 2016*

2016*
Deceased Organ Donors 9,884
Living Organ Donors 5,527
Waiting List Deaths 2,036

Source: Based on OPTN data as projected through 2016. Count based upon candidates.
U.S. Experience – Deceased Organ Donors

*By Donor Type*

1996 – 2015

Source: Based on OPTN data through December 31, 2015.
U.S. Deceased Organ Donors
By Cause of Death – CVA Only
1995 – 2015

Source: Based on OPTN data as through December 31, 2015.
U.S. Deceased Organ Donors
By Cause of Death – Trauma Only
2000 – 2015

Source: Based on OPTN data through December 31, 2015.
U.S. Deceased Organ Donors

By Cause of Death – Anoxia Only

2000 – 2015

Source: Based on OPTN data through December 31, 2015.
Organ Donors by Cause of Death Trend

GLDP

# Organ Donors (Previous 12 Months)

Month / Year

Anoxia  Cerebrovascular/Stroke  Head Trauma

Other Causes of Death Excluded
GLDP Anoxic Organ Donors w/ Cardiovascular Mechanism of Death Trend

Organ Donors - Cardiovascular Deaths (Previous 12 Months)

Month / Year
GLDP Anoxic Organ Donors w/Drug Overdose Mechanism of Death Trend
Deceased Donor Kidneys Recovered in the U.S.
1/1/2000 – 10/31/2016

Discarded

<table>
<thead>
<tr>
<th>Year</th>
<th>Kidneys Recovered</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>1,627</td>
</tr>
<tr>
<td>2001</td>
<td>1,578</td>
</tr>
<tr>
<td>2002</td>
<td>1,668</td>
</tr>
<tr>
<td>2003</td>
<td>2,084</td>
</tr>
<tr>
<td>2004</td>
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<td>2006</td>
<td>2,630</td>
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<td>2007</td>
<td>2,608</td>
</tr>
<tr>
<td>2008</td>
<td>2,763</td>
</tr>
<tr>
<td>2009</td>
<td>2,641</td>
</tr>
<tr>
<td>2010</td>
<td>2,646</td>
</tr>
<tr>
<td>2011</td>
<td>2,763</td>
</tr>
<tr>
<td>2012</td>
<td>2,734</td>
</tr>
<tr>
<td>2013</td>
<td>2,888</td>
</tr>
<tr>
<td>2014</td>
<td>3,157</td>
</tr>
<tr>
<td>2015</td>
<td>3,264</td>
</tr>
<tr>
<td>2016</td>
<td></td>
</tr>
</tbody>
</table>
58 OPO Donation Service Areas in the U.S.
321 million people – 9,080 Deceased Donors (2015)
5,988 Living Donors (2015)
30,973 Transplants (2015)

OPO Data
Population Bases from 1.3 Million to 19.8 Million
Deceased Donors Recovered ranged from 40 to 483 Donors
Donors per million (DPM) ranged from 17.0 to 44.0; U.S. Average 29.4
§486.324(a)- While an OPO may have more than 1 board, the OPO must have an advisory board that has both the authority described in paragraph (b) of this section and the following membership:

- §486.324(a)1- Members who represent hospital administrators, either intensive care or emergency room personnel, tissue banks, and voluntary health associations in the OPO’s DSA
- §486.324(a)2- Individuals who represent the public residing in the OPO’s DSA
- §486.324(a)3- A physician with knowledge, experience, or skill in the field of human histocompatibility or an individual with a doctorate degree in biological science and with knowledge, experience or skills in the field of human histocompatibility
- §486.324(a)4- A neurosurgeon or other physician with knowledge or skills in the neurosciences
- §486.324(a)5- A transplant surgeon representing each transplant hospital in the service area with which to OPO has arrangements to coordinate its activities. The transplant surgeon must have practicing privileges and perform transplants in the transplant hospital represented
- §486.324(a)6- An organ donor family member
Central Oversight Committee

I

Scientific Merit Workgroup

II

Ethical Oversight Workgroup

**Deceased Donor Review

Recipient Human Subject Assessment

No

Non-Human Subject Review

Yes

Human Subject Review (IRB Function)

Approve

III

Safety and Impact Monitoring Workgroup

**Deceased donor is NOT a human subject**
OPOs

PUBLIC
TRUST

Donor
Hospitals

Transplant
Centers
U.S. Organ Donor Experience – DBD & DCD Donors

2002 – 2016 (projected through year end 2016)

Total Deceased Organ Donors = 119,542

BD (n=106,137)  DCDs (n=13,405)

0  2,000  4,000  6,000  8,000  10,000

NUMBER OF ORGAN DONORS

YEAR

2016
2015
2014
2013
2012
2011
2010
2009
2008
2007
2006
2005
2004
2003
2002

Non-Heart-Beating Organ Transplantation

Practice and Protocols

Meeting Summary – December 20, 2006

Moving Forward in Increasing Organ Donation: Opportunities and Barriers to Uncontrolled DCD in Major Metropolitan Cities

...
Transplant recipients may be participating in clinical studies designed to improve transplant outcomes.

If the gifts cannot be used for transplantation or therapy, I authorize their use for research and/or education purposes.

Management of the donor may include research measures designed to study ways of improving organ transplant outcomes.
GTEx Pilot Project Participants

- Three biospecimen source sites to collect tissues; GLDP, LifeNet of Virginia, Drexel University College of Medicine.
- A laboratory data analysis center
- A coordinating center, led by the National Cancer Institute's Cancer Human Biobank (caHUB)
  - Specimens shipped to caHUB
  - A portion of each sent to the laboratory, data analysis center, and coordinating center for molecular analysis.
# Ideal Process for Organ Donation

<table>
<thead>
<tr>
<th>Education (General Public / Healthcare Professionals)</th>
<th>Detection/Declaration of Death/Referral to OPO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Donor Evaluation by OPO Coordinator</td>
<td>Family Approach/Consent</td>
</tr>
<tr>
<td>Clinical Donor Management</td>
<td>Matching/Allocation</td>
</tr>
<tr>
<td>Surgical Recovery/Preservation/Transportation</td>
<td>Transplantation</td>
</tr>
<tr>
<td>Case Follow-Up</td>
<td></td>
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</tbody>
</table>
“The care of the potential donor is essentially the simultaneous care of multiple recipients.”

Source:
Aggressive Care Plan

From the moment brain death is declared, the emphasis shifts from saving the patient’s life, to maintaining the family’s option to donate by optimizing end-organ function for possible transplantation.

- Hypotension
- Impaired Gas Exchange
- Hypothermia
- Oliguria
- Excessive Urinary Output
- Oxygenation
- Acid Base Abnormalities
- DIC
- Electrolyte Imbalances
- Hormonal Changes
U.S. SRTR Adjusted OPO OTPD Model
1/1/2014 – 12/31/2015

OTPD Significantly Higher Than Expected
OTPD as Expected
OTPD Significantly Lower Than Expected

Source: SRTR
Organ Allocation

- Pre-Recovery
- Intra-Operative
- Post-Recovery
OPO Begins Organ Offer Process

OPO sends an electronic notification to a selected range of potential recipients. The primary contact for each transplant center will receive a voice and text notification.

OPO sends out electronic notifications on the match results page.

Prominent display of donor blood type.

The candidate with the primary offer is highlighted.
% High Risk Organ Donor Trend
GLDP Rolling 12 month avg
15.3 Informed Consent of Transmissible Disease Risk

Transplant programs must obtain specific informed consent before transplant of any organ when any of the following occurs:

- The donor has a known medical condition that may, in the transplant hospital’s medical judgment, be transmissible to the recipient, including HIV.
- The donor meets any of the criteria for increased risk of transmitting HIV, hepatitis B, and hepatitis C as specified in the U.S. Public Health Services (PHS) Guideline.
- When a hemodiluted specimen is used for donor HIV, hepatitis B, or hepatitis C screening, according to Policy 2.5: Hemodilution Assessment.

Transplant programs must also inform potential candidates of the general risks of potential transmission of malignancies and disease from organ donors, including all of the following information:

1. Deceased donors are evaluated and screened as outlined in Policy 2.3: Evaluating and Screening Potential Deceased Donors.
2. Living Donors are required to undergo screening for the diseases listed in Policy 14.4: Medical Evaluation Requirements for Living Donor.
3. That there is no comprehensive way to screen deceased and living donors for all transmissible diseases.
4. That transmissible diseases and malignancies may be identified after transplant.

The transplant program must do both of the following:

1. Explain these risks and obtain informed consent from the potential candidate or candidate’s agent before transplant.
2. Document consent in the potential candidate’s medical record.

15.3.A Donors with Additional Risk Identified Pre-transplant

If additional donor disease or malignancy transmission risk is identified pre-transplant, the transplant program must do all of the following:

1. Explain the risks and obtain informed consent from the potential transplant recipient or the potential recipient’s agent before transplant.
2. Document this consent in the potential recipient’s medical record.
3. Follow any recipient of the deceased or living donor organs for the development of potential donor-derived disease after transplantation.

15.3.B Donors at Increased Risk for Transmission of Blood-borne Pathogens

If a donor is found to have an increased risk for transmitting blood borne pathogens, the transplant program must offer recipients of the donor organs all of the following in addition to routine post-transplant care:

1. Additional post-transplant testing for HIV, hepatitis C, and hepatitis B as appropriate based on the recipient’s pre-transplant status. Every transplant hospital must develop and implement a written protocol for post-transplant testing for these diseases.
2. Treatment of or prophylaxis for the transmissible disease, when available.
Summary

- Donor Pool and Utilization Challenge Require DIR to increase transplants
- Guidance for Donor Hospital Policies
- Central Oversight to Assist Researchers & OPOs
- Organ Allocation Dynamics