An Introductory Course for the NEW Transplant Professional & Procurement Professional

June 15-18, 2012
Tempe Mission Palms Hotel and Conference Center
Tempe, Arizona

The Organ & Tissue Recovery Process

www.natco1.org
Program Schedule

An Introductory Education Course for the NEW Transplant or Procurement Professional
Tempe Mission Palms Hotel & Conference Center • June 15-18, 2012

Friday, June 15, 2012

12:00 – 5:00 p.m.
Registration Open – Foyer D & E

PLENARY SESSION – Palm Ballroom A/B/D/E

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<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Speaker</th>
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<tbody>
<tr>
<td>2:00 – 2:30 p.m.</td>
<td>Welcome &amp; Opening Remarks</td>
<td>Kara Ventura, DNP, PNP, DCC, CCTC Michael Kaiser, RN, CPTC</td>
</tr>
<tr>
<td>2:30 – 3:00 p.m.</td>
<td>What Do Those OTHER People Do?</td>
<td>Kara Ventura, DNP, PNP, DCC, CCTC Michael Kaiser, RN, CPTC</td>
</tr>
<tr>
<td>3:00 – 4:15 p.m.</td>
<td>Donation after Cardiac Death</td>
<td>Shannon Kaminski, RN, CPTC</td>
</tr>
<tr>
<td>4:15 – 4:30 p.m.</td>
<td>REFRESHMENT BREAK – Courtyard Kiosk</td>
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<tr>
<td>4:30 – 5:30 p.m.</td>
<td>Investing in Donation &amp; Transplantation</td>
<td>P.J. Geraghty, EMT-P, BS, CPTC Lauren Rutledge, BS</td>
</tr>
<tr>
<td>5:30 – 7:00 p.m.</td>
<td>Introduction to Transplant Ethics</td>
<td>Courtenay Bruce, JD, MA</td>
</tr>
<tr>
<td>7:00 – 8:30 p.m.</td>
<td>Welcome Reception – Cloister</td>
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</table>
**Saturday, June 16, 2012**

6:45 – 8:00 a.m.
Continental Breakfast available – Courtyard Kiosk

7:00 a.m. – 4:30 p.m.
Registration Open – Foyer D & E

### BREAKFAST SESSION – Palm Ballroom A/D

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<tr>
<th>Time</th>
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<tbody>
<tr>
<td>7:30 – 8:00 a.m.</td>
<td>ABTC Certification for Transplant Coordinators: Your Certification Questions Answered Breakfast available in the Courtyard Kiosk</td>
<td>Sue Dummer, RN, BSN, MBA, CCTN</td>
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</tbody>
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### CONCURRENT SESSIONS

#### Transplant Track – Palm Ballroom A/D

<table>
<thead>
<tr>
<th>Time</th>
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<tbody>
<tr>
<td>8:00 – 9:45 a.m.</td>
<td>Immunology &amp; Histocompatibility</td>
<td>Jonah Odim, MD, PhD, MBA</td>
</tr>
<tr>
<td>9:45 – 10:00 a.m.</td>
<td>REFRESHMENT BREAK – Courtyard Kiosk</td>
<td></td>
</tr>
<tr>
<td>10:00 – 11:30 a.m.</td>
<td>Infectious Diseases in Transplantation</td>
<td>TBD</td>
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<tr>
<td>11:30 a.m. – 12:30 p.m.</td>
<td>GROUP LUNCHEON – Cloister</td>
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<tr>
<td>12:30 – 1:45 p.m.</td>
<td>Mechanisms of Rejection</td>
<td>Jonah Odim, MD, PhD, MBA</td>
</tr>
<tr>
<td>1:45 – 3:00 p.m.</td>
<td>Care of the Heart Transplant Recipient</td>
<td>Jennifer Reese, RN, MSN, NP-C</td>
</tr>
<tr>
<td>3:00 – 3:15 p.m.</td>
<td>REFRESHMENT BREAK – Courtyard Kiosk</td>
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</tr>
<tr>
<td>3:15 – 4:30 p.m.</td>
<td>Care of the Lung &amp; Heart-Lung Transplant Recipient</td>
<td>Kieran D. Ryan, RN, BS, CCTC, CPTC</td>
</tr>
<tr>
<td>4:30 – 5:00 p.m.</td>
<td>Thoracic Transplant Open Forum</td>
<td>Jennifer Reese, RN, MSN, NP-C</td>
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</tbody>
</table>

#### Procurement Track – Palm Ballroom E

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Speaker</th>
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<tbody>
<tr>
<td>8:00 – 9:15 a.m.</td>
<td>Infectious Disease Assessment in the Organ Donor</td>
<td>TBD</td>
</tr>
<tr>
<td>9:15 – 9:30 a.m.</td>
<td>REFRESHMENT BREAK – Courtyard Kiosk</td>
<td></td>
</tr>
<tr>
<td>9:15 a.m. – 12:00 p.m.</td>
<td>Pediatric Donor Management &amp; Case Study Application</td>
<td>Thomas Nakagawa, MD, FAAP, FCCM</td>
</tr>
<tr>
<td>12:00 – 1:00 p.m.</td>
<td>GROUP LUNCHEON – Cloister</td>
<td></td>
</tr>
<tr>
<td>12:45 – 2:15 p.m.</td>
<td>Consent, If Only They All Said Yes</td>
<td>Michael Kaiser, RN, CPTC</td>
</tr>
<tr>
<td>2:15 – 2:30 p.m.</td>
<td>REFRESHMENT BREAK – Courtyard Kiosk</td>
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<tr>
<td>2:30 – 3:15 p.m.</td>
<td>Legal Alligators of Consent</td>
<td>Michael Kaiser, RN, CPTC</td>
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<tr>
<td>3:15 – 4:15 p.m.</td>
<td>Research &amp; Tissue</td>
<td>Frank Rathman, BS, CPTC</td>
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**Sunday, June 17, 2012**

7:00 – 8:00 a.m. **Continental Breakfast available – Courtyard Kiosk**

7:30 a.m. – 12:00 p.m. **Registration Open – Foyer D & E**

**CONCURRENT SESSIONS**

**Transplant Track – Palm Ballroom A/D**

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<tbody>
<tr>
<td>8:00 – 10:15 a.m.</td>
<td>Drug Therapy in Transplantation</td>
<td>Jeanne Chen, PharmD</td>
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<tr>
<td>10:15 – 10:30 a.m.</td>
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<td>REFRESHMENT BREAK – Courtyard Kiosk</td>
</tr>
<tr>
<td>10:30 – 11:15 a.m.</td>
<td>Living Donation in Liver Transplantation</td>
<td>Kara Ventura, DNP, PNP, DCC, CCTC</td>
</tr>
<tr>
<td>11:15 a.m. – 12:30 p.m.</td>
<td>Organ Allocation &amp; Recipient Issues</td>
<td>Lori Gore, BA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Estelle Willard, BS</td>
</tr>
<tr>
<td>12:00 p.m. – 1:00 p.m.</td>
<td></td>
<td>GROUP LUNCHEON – Cloister</td>
</tr>
<tr>
<td>1:15 – 2:30 p.m.</td>
<td>Liver Transplantation &amp; Allocation of Livers</td>
<td>Kara Ventura, DNP, PNP, DCC, CCTC</td>
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<tr>
<td>2:30 – 2:45 p.m.</td>
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<td>REFRESHMENT BREAK – Courtyard Kiosk</td>
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<tr>
<td>2:45 – 3:45 p.m.</td>
<td>Intestinal Transplantation</td>
<td>Patricia Harren, RN, DNP, CCTC</td>
</tr>
<tr>
<td>3:45 – 4:15 p.m.</td>
<td>Abdominal Transplant Open Forum</td>
<td>Kara Ventura, DNP, PNP, DCC, CCTC</td>
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<td>Patricia Pavlak, RN, BSN, CCTC, CPTC</td>
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**Procurement Track – Palm Ballroom E**

<table>
<thead>
<tr>
<th>Time</th>
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<tbody>
<tr>
<td>8:00 – 9:15 a.m.</td>
<td>Donor &amp; Recipient Histocompatibility</td>
<td>Jonah Odim, MD, PhD, MBA</td>
</tr>
<tr>
<td>9:15 – 10:30 a.m.</td>
<td>Organ Allocation Donor Issues</td>
<td>Lori Gore, BA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Estelle Willard, BS</td>
</tr>
<tr>
<td>10:30 – 10:45 a.m.</td>
<td></td>
<td>REFRESHMENT BREAK – Courtyard Kiosk</td>
</tr>
<tr>
<td>10:45 a.m. – 12:45 p.m.</td>
<td>Donor Physical Assessment</td>
<td>Edmundo Ferreol, MD, CTBS</td>
</tr>
<tr>
<td>12:00 – 1:00 p.m.</td>
<td></td>
<td>GROUP LUNCHEON – Cloister</td>
</tr>
<tr>
<td>1:30 – 3:00 p.m.</td>
<td>Quality of Hospital Services</td>
<td>Hedi Aguiar, RN, CCRN, BA</td>
</tr>
<tr>
<td>3:00 – 3:15 p.m.</td>
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<td>REFRESHMENT BREAK – Courtyard Kiosk</td>
</tr>
<tr>
<td>3:15 – 4:45 p.m.</td>
<td>Operating Room &amp; Organ Preservation Techniques</td>
<td>Frank Rathman, BS, CPTC</td>
</tr>
</tbody>
</table>
**Monday, June 18, 2012**

7:00 – 8:00 a.m. Continental Breakfast available – Courtyard Kiosk

**CONCURRENT SESSIONS**

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<tr>
<td>8:00 – 9:00 a.m.</td>
<td>Pediatric Transplantation</td>
<td>Patricia Harren, RN, DNP, CCTC</td>
</tr>
<tr>
<td>9:00 – 10:15 a.m.</td>
<td>Kidney Transplantation &amp; Allocation of Kidneys</td>
<td>Patricia Pavlak, RN, BSN, CCTC, CPTC</td>
</tr>
<tr>
<td>10:15 – 10:30 a.m.</td>
<td>REFRESHMENT BREAK – Courtyard Kiosk</td>
<td></td>
</tr>
<tr>
<td>10:30 – 11:30 a.m.</td>
<td>Living Donation in Kidney Transplantation</td>
<td>Patricia Pavlak, RN, BSN, CCTC, CPTC</td>
</tr>
<tr>
<td>11:30 a.m. – 12:30 p.m.</td>
<td>Pancreas &amp; Islet Cell Transplantation</td>
<td>Patricia Pavlak, RN, BSN, CCTC, CPTC</td>
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</tbody>
</table>

### Procurement Track – Palm Ballroom E

<table>
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<tr>
<th>Time</th>
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</thead>
<tbody>
<tr>
<td>8:00 – 12:00 p.m.</td>
<td>Dynamics of Adult Donor Management</td>
<td>Harry E. Wilkins III, MD, FACS, MHCM</td>
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<tr>
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<td>John Belcher, BS, CCEMT-P, CTBS, CPTC</td>
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<tr>
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<td></td>
<td>John T. Nguyen, RN, CCRM</td>
</tr>
<tr>
<td>10:00 – 10:15 a.m.</td>
<td>REFRESHMENT BREAK – Courtyard Kiosk</td>
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</tbody>
</table>
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Exhibitors will be available to discuss their products and answer your questions during the NATCO Introductory Education Course. Exhibit hours are as follows:

**Saturday, June 16**
11:15 a.m. – 2:15 p.m.

**Sunday, June 17**
11:30 a.m. – 1:30 p.m.

**Monday, June 18**
10:00 a.m. – 12:00 p.m.

**NATCO INTRODUCTORY EDUCATION COURSE EXHIBITORS**

**International Institute for the Advancement of Medicine (IIAM)**
1232 Mid-Valley Drive
Jessup, PA
570-496-3441
[www.iiam.org](http://www.iiam.org)

The International Institute for the Advancement of Medicine (IIAM) provides normal and diseased, non-transplantable, human tissues consented for medical research and education. Working with 60 recovery programs, IIAM receives almost 7,000 referrals of fresh organs to its Organ Division, and recovers over 2,000 cadaveric specimens from its Anatomical Division annually.

**Organ Recovery Systems**
2570 East Devon Avenue
Des Plaines, IL 60018
847-824-2465
[www.organ-recovery.com](http://www.organ-recovery.com)

Organ Recovery Systems develops innovative technologies and services to improve the quality and quantity of organs, tissues and cells for transplantation. The company makes the award-winning LifePort® Kidney Transporter and provides regional perfusion services that help transplant centers worldwide evaluate and treat kidneys, and soon pancreas, heart and liver.
Core Competencies for the Procurement Transplant Coordinator
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Assumption Statements

This document outlines the core competencies for practitioners/coordinators in the field of organ and tissue procurement; and hospital services/development.

These general practitioner/coordinator competencies are broad in scope to acknowledge the diverse professional practices unique to each organ and tissue procurement organization.

These competencies are meant to be applicable to both adult and pediatric donors.

LEGEND

# Competency Category

Competency Statement(s)

Specific core competencies of behaviors/tasks/responsibilities

• Subcategories of behaviors/tasks/responsibilities

The Procurement Coordinator maintains patient records, both donor and recipient, in compliance with the Health Insurance Portability and Accountability Act (HIPAA) regulations.

1. Hospital Development (HD) and Professional Education

The Procurement Transplant Coordinator (PTC) works within assigned hospitals to promote an effective donation system. Ensuring key elements include the referral of all potential organ and tissue donors to the Organ Procurement Organization (OPO), analysis and application of donation specific data; establishing a customized donation awareness program; education and development of relationships at all levels. The PTC is responsible for continuous improvement to effectively facilitate the donation process and meet the needs of the hospital and community.

The PTC

Analyzes each hospital’s organ and tissue donor potential through regularly scheduled patient death record reviews (DRRs), optimally done in real time and coordinates with actual referral activity data.

Develops a demographic profile for each hospital, including data relative to key contacts, donation trends, education and quality improvement activities.

Identifies and meets with key hospital personnel and physicians who may impact the donation process. Ensures support of senior leadership, physician and clinical champions while building effective relationships.

Involves key leadership within the hospitals to generate effective strategies for results. Collaborates with identified liaisons from the hospital staff from ER, ICU, OR and other key contacts, including physicians, to ensure an effective donation system.

Establishes organ and tissue donation policies and procedures (P & Ps) with key hospital personnel, and assists in reviewing and/or revising P & Ps as they relate to ongoing donation program needs.

Collaborates with medical staff to ensure current P & Ps for the determination of death follow state regulations.

Identifies physicians from appropriate medical departments/specialties (i.e., Neurosurgery, Neurology, Emergency Medicine, Trauma) where there is significant opportunity for donor referral and/or management and meets to discuss donation process and a coordinated plan.

Establishes in collaboration with the hospital a strategic business plan which customizes the donation process and allows efficient processes. Modifies plans as necessary to meet the mutually established goals for education, conversion and quality.

Establishes a written agreement, “Memorandum of Understanding” (MOU), or equivalent document between the hospital and organ/tissue procurement organization (OPO) which formalizes the business relationship between entities.

Establishes a referral mechanism in which early referral of potential organ donors is made based upon mutually acceptable clinical triggers for imminent death.

Establishes a consent process for each organ and tissue referral based upon hospital policy and best practices for donation, including an effective request process.

Utilizes death record review/mortality data to evaluate the performance of the donation process in all assigned hospitals. Establishes a plan with the hospital to determine root causes for variance to policies or expected donation outcomes. Provides feedback to key personnel and makes recommendations for improvements on the hospital’s statistical performance of the donation program, if needed.

Compiles and maintains a hospital-specific file that includes, but is not limited to, demographic profile, P & Ps, educational programs, activities, contacts, compliance statistics, and the HD strategic business plan.

Conducts public and professional organ and tissue donation educational activities in support of public and professional target groups:

• Identifies target groups to assess and prioritize the need for education
• Develops education programs and materials for specific target groups
• Provides education programs for target groups
Coordinates professional education activities with other organizations involved in donation or transplantation.

Reviews written evaluations from formal and informal educational presentations and incorporates changes as appropriate based upon written evaluations of professional education presentations.

Collaborates with the identified hospital donation liaison from the hospital staff to ensure an effective donation system.

Coordinates department/specialty communications to manage donor referral/management process with physician and clinical champions as appropriate.

Coordinates unit-specific educational programs and others as appropriate to meet the needs of the hospital.

2. Organ and Tissue Donor Evaluation

The PTC evaluates referrals for organ and tissue donor suitability based on OPO, OPTN/UNOS, AOPO and CDC guidelines/recommendations and other regulatory requirements.

The PTC:

- Responds to hospital’s referral of a potential donor as defined by AOPO, OPTN/UNOS, and others by telephone or on-site in a timely manner.
- Develops a plan with hospital staff for on-site evaluation of the potential donor in accordance with OPO and hospital protocols.
- Reviews the patient’s current and past medical records.
- Along with medical oversight from the OPO, determines potential for organ and tissue donation after brain or cardiac death.
- Works in conjunction with local tissue and eye banks to ensure recovery of all usable consented tissues.
- Determines if conditions exist that may influence donor acceptance.
- Identifies and documents the presence of past or present malignancies, including primary brain tumors, and all surgical intervention/treatments.
- Identifies and documents all other surgical intervention/treatments.
- Identifies and documents the presence of current or recent infectious conditions.
- Identifies and documents confirmed human immunodeficiency virus antibody sero-positive results.
- Identifies and documents high-risk behaviors for viral transmission as outlined by the Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), and OPO protocols.

Documents hospital and pre-hospital course (referring site and transport).

Documents transport/OR/special procedures (DPL, CT, MRI).

Identifies and documents traumatic injuries directly impacting specific organs and tissue.

Documents and diagrams associated injuries.

Documents all resuscitation/downtime including treatments.

 Screens potential donors based on established OPO and OPTN/UNOS guidelines in consultation with OPO medical director and/or administrators on call.

Implements the procedure for decision making regarding donor suitability.

Collaborates with hospital and other procurement staff to ensure the family will not be approached for organ and tissue donation when patient is determined to be medically unsuitable.

Differentiates between brain death and cardiac death:
- Recognizes the clinical criteria used for donation after cardiac death.
- Recognizes the clinical criteria used to diagnose brain death.

Recognizes extrinsic factors that may interfere with the diagnosis of brain death such as hypothermia, drugs affecting central nervous system (CNS) function and metabolic derangements.

Evaluates and assesses criteria used to diagnose brain death.

Understands the use of confirmatory tests used to diagnose/confirm brain death.

Assures adequate documentation of brain death through medical record documentation by physician, including date, time of death, criteria used, statement of brain death, and physician(s) signature(s).

Collaborates with appropriate hospital staff to report the death to the medical examiner (ME) or coroner.

Documents pre-mortem report to ME/coroner, with physician, in cases of potential donation after cardiac death (DCD).

Documents ME/coroner release or restrictions to donation in the patient’s medical record, as well as the donor record, including ME/coroner name, date/time of contact, and requests for blood, records, and restriction details.

Obtains pre- and/or post-transfusion serum/blood specimens for serological testing.
Coordinates serological testing with a Clinical Laboratories Improvement Amendments (CLIA)-certified laboratory/technician and determines timing of results.

Obtains blood sample for ABO-blood typing/sub-typing and crossmatching for blood products as necessary.

Obtains a hard copy of the ABO blood type (subtypes) and any additional ABO confirmation(s) as required.

Obtains an accurate weight and height.

Registers donor with OPTN/UNOS and obtains identification number and donor-specific organ and tissue allocation lists.

Obtains blood and/or inguinal lymph nodes for the tissue-typing laboratory(s) to ascertain human leukocyte antigen (HLA) and crossmatching requirements in accordance with OPO and OPTN/UNOS requirements.

Obtains a surgical consult to recover inguinal lymph nodes as necessary.

Documents donor physical exam (after declaration and ME/coroner clearance per OPO/local protocol).

Performs/obtains all pertinent tests/consults to assess general and organ and tissue specific suitability and documents the results in the donor record.

Documents all general and organ and tissue specific tests in accordance with OPTN/UNOS/medically-related standards. See Appendix A for recommended test(s).

Identifies abnormal trends in laboratory results.

Reviews and documents toxicology results.

Assesses and documents current and cumulative hydration status and urine/total output.

Documents:
• all blood products received
• medications, pressors, and drips
• vital sign trends
• results of cardiac consult including 12 lead EKG, CXR, arterial blood gases (ABGs), cardiac enzymes (CPK with MB fraction, troponin), echocardiogram, and cardiac catheterization
• results and interpretation of pulmonary consult/evaluation including CXR, ABGs (serial and with O2 challenge), sputum culture with gram stain, lung/chest measurements as necessary, and bronchoscopy, and considers CT scan when indicated by medical history and clinical request
• serial ABGs including all ventilator settings

Assesses and documents:
• hemodynamic profile
• cultures and sensitivities
• need for antibiotic therapy

Obtains copies of CXR, echocardiogram, and catheterization films/tapes/disks/CDs.

Obtains a hard copy of serology results and documents the results in the donor record.

Reports positive serology results in accordance with OPO and OPTN/UNOS guidelines.

3. Family Approach and Informed Consent

The PTC ensures that the legal next-of-kin (NOK) is provided the option of organ and tissue donation in a sensitive and caring manner that meets his/her emotional and cultural needs.

The PTC

Is highly skilled in communication and conflict resolution.

Understands the grieving process of families faced with the sudden death of a loved one.

Communicates with the physician and hospital staff to learn of the patient’s clinical status and family’s understanding of the clinical condition.

Collaborates with physician and hospital staff to ensure the family understands the hopelessness of the patient’s clinical condition prior to the discussion of donation.

Identifies the patient’s legal next-of-kin in accordance with state and Uniform Anatomical Gift Act (UAGA) statutes and understands that legal next-of-kin may not necessarily be the decision maker.

Determines specific cultural and religious beliefs of the patient/patient’s family.

Determines need for language interpreter and ensures the use of a professional interpreter if needed.

Establishes an optimal climate or environment for the collaborative approach to offer the option of organ and tissue donation.

Makes an appropriate introduction to the patient’s family.

Extends sympathy to the patient’s family.

Evaluates and assesses the family’s understanding of the entire situation: injuries, brain death testing, and results of testing.

Evaluates and ensures the family understands brain death and responds appropriately to their questions.

Provides the family with an overview of their options for donation.

Dispels myths surrounding the organ and tissue donation process.

Asks probing questions to ascertain the family’s understanding of the information provided about the donation process.
Addresses the family’s questions, concerns, and needs.

Supports the family regarding the donation decision (utilizes donor registry status, previous stated wishes by the patient, which may be different from family).

Ensures the family understands the need for all evaluation procedures, which organs and tissue will be recovered, and the timing of the entire donation process.

Explains the consent form and obtains informed consent.

Ensures written documentation of the in-person, telephone, or translated consent in the patient’s medical record as well as the donor record.

Discusses plan for follow-up contact with the family, before and after the surgical organ and tissue recovery.

Explains the medical examiner’s possible involvement during or after the donation process.

Oﬀers the family resources as available and desired (i.e., support with funeral arrangements, victim services, grief literature, etc.)

Recognizes own limitations and requests additional support and resources as needed and available.

Understands that families may occasionally decline donation when the option of donation is presented at an inappropriate time or in an insensitive manner, and considers re-approaching the family after evaluating their emotional and physical needs.

### 4. Medical/Social History Interview

The PTC identiﬁes organ and tissue-speciﬁc and behavioral risk factors utilizing all available resources.

The PTC

Conducts Past Medical/Social History (PM/SH) interviews sensitively and in a private setting.

Conducts PM/SH interview with family members and/or signiﬁcant life partners to obtain a medical and social behavioral history. Documents the results of the interview as accurately and with as much probing detail as possible.

Obtains PM/SH from other sources when indicated/necessary and possible.

Seeks additional information from primary care physician(s), surgeon(s) who performed past procedure(s), pathology results, old medical records, or other identiﬁed sources.

### 5. Medical-Legal Activities

The PTC ensures that all medical and legal requirements are met prior to organ and tissue recovery.

The PTC

- Reviews hospital brain death policy on all potential organ donors.
- Reviews hospital donation after cardiac death (DCD) policy on potential DCD organ donors.
- Communicates with declaring physician to ensure documentation of:
  - date of death
  - time of death
  - a statement that patient meets criteria for brain death
  - physician’s signature
- Assures that appropriate documentation of brain death or death by cardiopulmonary criteria is obtained and placed in the donor record.
- Obtains and documents ME/coroner clearance for organ and tissue donation in accordance with local statutes.
- Complies with, and clearly documents ME/coroner’s requests for limitations on organ and tissue donations.
- Coordinates on-site ME/coroner/police request for pre-recovery and intra-operative examinations.
- Complies with ME/coroner’s requests for donor record documentation and specimens.
- Assures written documentation of legal next of kin’s informed consent to organ and tissue donation is obtained, whether obtained in person or phone/fax facilitated.
- Assures that the consent document is placed in the patient’s medical record as well as the donor record.
- Assures compliance with all applicable hospital policies, local, state, and federal statutes/regulations.

### 6. Organ Donor Management

The PTC endeavors to physiologically manage the donor to achieve optimal organ function. The PTC is knowledgeable of the pathophysiologial sequelae of brain death.

The PTC

- Requests arterial line.
- Requests insertion of pulmonary arterial catheter (PA) or central line or similar minimally invasive device.
Assesses/interprets PA line/CVP measurements.
Obtains information from the PA line and documents the data in the donor record.
Assesses ongoing hemodynamics.
Assesses need for and effectiveness of vasopressor support.
Recognizes hypotension.
Titrates vasopressor dosage according to hemodynamics, and evaluates effectiveness of intervention.
Recognizes arrhythmias, significance and implements specific treatment.
Recognizes hypertension.
Titrates anti-hypertensive medication appropriately.
Assesses hydration status.
Adjusts intravenous fluids (IVFs) according to hydration status.
Recognizes hypo/hypervolemia.
Adjusts IVF volumes according to pulmonary arterial and central venous pressures.
Adjusts IVF composition according to laboratory results.
Recognizes laboratory trends and/or abnormalities and recommends appropriate interventions.
Recognizes hypo/hyperglycemia.
Administers insulin according to serum glucose levels.
Recognizes and intervenes to correct acid base imbalances.
Administers sodium bicarbonate or alternate agent (THAM) according to ABGs.
Recognizes hypercapnia by ABGs and treats by adjusting mechanical ventilator settings or considers lung volume recruitment maneuvers per regional protocols.
Recognizes hypoxemia by review of ongoing clinical condition.
Treats hypoxemia by adjusting mechanical ventilator settings as indicated by ABGs.
Recognizes blood component deficiencies and coagulopathies.
Transfuses with appropriate blood products according to hematology and coagulation test results.
Administers and titrates IVF, colloids, and vasopressor(s) appropriately.
Administers hormonal replacement therapies per OPO protocol.
Recognizes diabetes insipidus (DI).
Administers aqueous vasopressin/DDAVP as indicated for DI.
Recognizes electrolyte imbalances.
Adjusts IV fluid composition according to electrolyte abnormalities.
Recognizes oliguria.
Checks urinary catheter, adjusts IV fluids, and/or administers diuretics.
Recognizes actual/potential infection.
Administers appropriate antibiotic therapy and seeks guidance PRN.
Maintains normothermia via warming/cooling blanket/device(s), as necessary.

7. Organ Allocation

The PTC ensures that donated organs are allocated in an efficient and timely manner in accordance with OPO and OPTN/UNOS policies.

The PTC
Verifies accuracy of ABO typing, weight and height.
Registers the donor with OPTN/UNOS and generates a donor specific list (match run).
Ensures entry of organ-specific information into DonorNet to allow appropriate allocation decisions by accepting transplant programs.
Provides complete and accurate documentation of donor information to recipient centers.
Emphasizes any donor information that may be classified as high-risk or expanded donor criteria.
Ensures that organs are offered in accordance with organizational and national policies.
Allocates extra-renal organs in accordance with OPTN/UNOS policy or OPTN/UNOS approved local/regional variance.
Makes primary extra-renal organ offers (and back-up offers as per OPO protocols).
Documents acceptance/refusal of organ offer on donor specific list.
Documents appropriate OPTN/UNOS acceptance/refusal codes via DonorNet.
Allocates kidneys in accordance with OPTN/UNOS policy or OPTN/UNOS approved local/regional variance.
Documents appropriately any variance from approved policies.
8. Surgical Recovery and Organ and Tissue Preservation

The PTC ensures organs and tissue will be recovered to maximize utilization in accordance with OPO and OPTN/UNOS policies. The PTC preserves organs and tissue according to OPO and national standards to ensure maximum viability for transplantation.

The PTC

Coordinates operating room (OR) time with nursing and anesthesia staff.

Assists the OR staff as necessary, before, during, and after all recovery and preservation procedures, including post-mortem care.

Assures patient ID band is in place.

Prepares OR and anesthesia staff for organ and tissue recovery procedure(s) by providing a pre-operative briefing and written guidelines.

Discusses contingency procedures for hemodynamic/pulmonary instability with anesthesia staff.

Obtains surgical privileges for visiting surgeons, when needed, and provides a copy of all OPO and surgical personnel names and credentials to the circulator.

Assures brain death, ME/coroner authorization, blood type and consent documentation are in the medical record before the operative procedure begins and makes hospital staff and surgeons aware of complete documentation.

Assures medical record(s) and ID plate/alternative accompanies donor to the OR.

Arranges and coordinates safe/monitored transport of the donor to the OR.

Assures availability of proper instruments, equipment, and supplies during the surgical recovery.

Assures adequate supply of sterile saline slush for topical cooling.

Requests the need for sterilization of specialized organ and tissue recovery instruments.

Coordinates transportation of recovery teams in a timely and cost efficient/approved manner to the donor hospital.

Introduces OPO and surgical recovery personnel to the OR and anesthesia staff.

Assures a coordinated and informed plan for the sequence of recovery events between all surgical personnel.

Ensures a surgical time-out is called for OPO and hospital to confirm correct information for patient identification and surgical recovery.

Monitors and documents blood pressure, heart rate, and urine output.

Monitors and documents intravenous fluids, transfusions, and medications.

Observes universal precautions throughout the entire surgical recovery procedure.

Assists in surgical recovery procedures as required by specific situation and OPO protocols.

Implements appropriate organ and tissue-specific preservation procedures.

Prepares, hangs, monitors, and records type, characteristic and volume of preservation solution(s).

Assures proper documentation of extra-renal organ and tissue anatomy and abnormal findings.

Assures proper documentation of each organ and tissue and archiving.

Obtains a copy of the anesthesia record.

Obtains an intra-operative ABG and records results in the donor record.

Makes copies of the completed donor record for all teams/staff and to accompany each organ and tissue.

Assures proper documentation of all intra-operative biopsy/pathology results.

Assures inclusion of vascular grafts as required with packaged extra renal organs and tissue.

Completes all documentation requirements to include, but not limited to, OR entry, incision, cross-clamp, and exit from OR times.

Distributes tissue-typing specimens to accompany each organ and tissue as necessary.

Assures proper packaging and labeling of organs and tissue typing materials according to OPO, OPTN/UNOS and OSHA standards.

Arranges for, or escorts teams out of hospital to awaiting transport to transplant center.

Arranges and conducts timely transportation of organ(s), tissue typing material, and donor documentation to the appropriate transplant center(s) and histocompatibility laboratories.

Communicates with local tissue and eye banks regarding timing/requirements (i.e., blood specimens, nodes, etc.) for tissue and eye donation as per local protocols.

Assures proper post-mortem care.
Assures original consent form and operative report remains with the patient's medical record as per OPO protocols.

Assures completion of operative report/note/procedures as required by donor hospital/OPO protocols.

Accompanies body to the morgue as necessary.

Assures proper documentation and blood samples for the ME/coroner when appropriate.

Communicates with:
- ME/coroner as arranged
- funeral home as arranged
- donor family as requested

9. Donor Records

The PTC maintains a permanent record of the organ and tissue donation in accordance with accepted confidentiality standards.

The PTC
- Assembles donor record and verifies inclusion of all documentation.
- Performs a quality assurance review of the donor record to verify accuracy and completion of all documents.
- Corrects errors in accordance with AOPO and/or OPO policies and guidelines.
- Submits information on organs and tissue transplanted and potential transplant recipient acceptance/refusal codes to OPTN/UNOS.
- Assures confidentiality of donor records.
- Complies with OPO, OPTN/UNOS, and Health Insurance Portability and Accountability Act (HIPAA) policies and procedures regarding documentation and maintenance of records.

10. Family Post-Donation Communication

The PTC understands and supports the needs of the grieving family and respects the donor family's wishes regarding notification of the donation outcome.

The PTC
- Complies with OPO, OPTN/UNOS, and HIPAA policies and procedures when communicating, either verbally or in writing, with donor families.
- Obtains recipient follow-up information.
- Provides follow-up calls to the donor family as agreed upon in the informed consent process.

Provides timely written communication to donor family regarding donation outcome within six weeks following the recovery of organs and tissue (or a time frame directed by OPO policy).

Ensures appropriate assignment of donation-related charges to the OPO.

Collaborates with transplant centers to facilitate anonymous correspondence between donor family and recipient(s) when mutually desired.

Offers support services to the donor family, which includes a specific number of contacts between the OPO and the family within the first 12 months following donation.

Facilitates donor family and recipient meetings within guidelines set forth by the OPO and transplant center(s).

11. Hospital Post-Donation Communication

The PTC notifies donor family and appropriate donor hospital staff of the donation outcome in a timely manner per OPO protocols.

The PTC
- Obtains recipient follow-up information.
- Provides follow-up calls and/or post donation visit to referring unit/site.
- Identifies participants in the organ and tissue referral, evaluation, management, and recovery process.
- Provides a post-donation conference/meeting/debriefing for all involved and/or interested hospital staff.
- Provides timely written communication to all involved hospital staff regarding donation outcome.
- Ensures appropriate assignment of donation-related charges to the OPO.
- Obtains final culture and sensitivities and reports results to transplant centers per OPO protocols.
- Communicates with funeral homes as indicated by the donor family and local protocols.
12. Professional Development

The PTC seeks to obtain increased knowledge to enhance individual performance in the organ and tissue procurement profession.

The PTC

- Obtains ABTC certification.
- Maintains ABTC certification.
- Reviews and integrates into practice the current professional literature in the procurement and hospital development field(s).
- Attends practice-related conferences and education offerings.
- Participates in professional transplant/donation organizations.
- Examines current procurement/HD-related research.
- Shares knowledge with newly hired PTCs through mentoring/precepting.
- Participates in and supports ongoing research within the OPO and publishes results as appropriate.

13. Professional Practice

The PTC conducts him/herself with the highest degree of professionalism in the organ and tissue procurement profession.

The PTC:

- Maintains the highest standards of professional conduct.
- Assures informed consent for organ and tissue donation.
- Protects the rights of patients, their families/legal guardians, and health care team members.

Respects individual privacy and holds confidential all information obtained in the course of action.

Assures open and clear communication with patients, families and health care team members without bias or discrimination.

Plans, conducts and evaluates educational activities for patients, families/legal guardians.

Plans, conducts and evaluates educational presentations, workshops, and seminars utilizing materials developed for professional education.

Assures that quality and performance improvement standards are implemented and maintained.

Evaluates self-performance by comparing actual outcomes to expectations.

Maintains current knowledge and complies with institutional policies and procedures.

Monitors hospital referrals and transplant outcomes to meet performance standards required by OPTN/UNOS, CMS, employer and personal expectations.

Maintains cooperative relationships with other health care professionals.

Acts to protect public trust when health care and safety are endangered.

Assists transplant centers and other community organizations with educational presentations and information appropriate to the needs of the various groups.

Reviews, evaluates and revises educational material and programs for donation and transplant practice.
## Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>ABG</td>
<td>Arterial Blood Gases</td>
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<td>ABTC</td>
<td>American Board for Transplant Certification</td>
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<td>ALT</td>
<td>Alanine Aminotransferase</td>
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<td>AOPO</td>
<td>Association of Organ Procurement Organizations</td>
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<td>AST</td>
<td>Aspartate Aminotransferase</td>
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<tr>
<td>Beta-HCG</td>
<td>Beta Human Chorionic Gonadotropin</td>
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<td>BUN</td>
<td>Blood Urea Nitrogen</td>
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<td>CDC</td>
<td>Centers for Disease Control and Prevention</td>
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<td>CLIA</td>
<td>Clinical Laboratory Improvement Amendments</td>
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<td>CMS</td>
<td>Centers for Medicare and Medicaid Services</td>
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<td>CMV</td>
<td>Cytomegalovirus</td>
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<tr>
<td>CNS</td>
<td>Central Nervous System</td>
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<tr>
<td>CPK</td>
<td>Creatine Phosphokinase</td>
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<tr>
<td>CT</td>
<td>Computed Tomography</td>
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<tr>
<td>CVP</td>
<td>Central Venous Pressure</td>
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<tr>
<td>CXR</td>
<td>Chest X-ray</td>
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<td>DCD</td>
<td>Donation after Cardiac Death</td>
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<td>DAVP</td>
<td>Desmopressin Acetate</td>
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<td>DI</td>
<td>Diabetes Insipidus</td>
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<td>DPL</td>
<td>Diagnostic Peritoneal Lavage</td>
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<td>DRR</td>
<td>Death Record Review</td>
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<td>EKG</td>
<td>Electrocardiogram</td>
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<td>FDA</td>
<td>Food and Drug Administration</td>
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<td>GGT</td>
<td>Gamma Glutamyl Transpeptidase</td>
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<td>HD</td>
<td>Hospital Development</td>
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<tr>
<td>HIPAA</td>
<td>Health Insurance Portability and Accountability Act</td>
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<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
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<td>HLA</td>
<td>Human Leukocyte Antigen</td>
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<td>HTLV</td>
<td>Human T-Cell Lymphotropic Virus</td>
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<tr>
<td>INR</td>
<td>International Normalized Ratio</td>
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<tr>
<td>IVF</td>
<td>Intravenous Fluid</td>
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<tr>
<td>MB</td>
<td>Isoenzyme of CPK</td>
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<tr>
<td>ME</td>
<td>Medical Examiner</td>
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<tr>
<td>MOU</td>
<td>Memorandum of Understanding</td>
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<tr>
<td>MRI</td>
<td>Magnetic Resonance Imaging</td>
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<tr>
<td>NATCO</td>
<td>NATCO, The Organization for Transplant Professionals</td>
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<tr>
<td>NOK</td>
<td>Next-of-Kin</td>
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<tr>
<td>OPO</td>
<td>Organ and Tissue Procurement Organization</td>
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<td>OPTN</td>
<td>Organ and Tissue Procurement and Transplant Network</td>
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<tr>
<td>OR</td>
<td>Operating Room</td>
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<tr>
<td>OSHA</td>
<td>Occupational Safety and Health Administration</td>
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<tr>
<td>PA</td>
<td>Pulmonary Arterial</td>
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<tr>
<td>P &amp; P</td>
<td>Policy and Procedures</td>
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<tr>
<td>PM/SH</td>
<td>Past Medical and Social History</td>
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<tr>
<td>PT</td>
<td>Prothrombin Time</td>
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<tr>
<td>PTC</td>
<td>Procurement Transplant Coordinator</td>
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<tr>
<td>PTT</td>
<td>Partial Thrombin Time</td>
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<tr>
<td>RPR</td>
<td>Rapid Plasma Reagin</td>
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<tr>
<td>SVR</td>
<td>Systemic Vascular Resistance</td>
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<tr>
<td>THAM</td>
<td>Tromethamine</td>
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<tr>
<td>UAGA</td>
<td>Uniform Anatomical Gift Act</td>
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<tr>
<td>UNOS</td>
<td>United Network for Organ Sharing</td>
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<tr>
<td>VDRL</td>
<td>Venereal Disease Research Laboratories</td>
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</table>
General: Complete blood count with differential, electrolytes (calcium, phosphorus, magnesium), ABO-typing, hepatitis screen, VDRL or RPR, FDA licensed anti-HIV I and II, anti-HTLV I and II, anti-CMV, blood and urine cultures, sputum culture as required, and chest X-ray. Beta HCG when gender appropriate.

Heart: 12-lead EKG, cardiology consult, chest X-ray, arterial blood gases (ABGs), cardiac enzymes (CPK with MB fraction, troponin), echocardiogram, and cardiac catheterization as defined by OPO/UNOS guidelines, and availability of this testing within the donor hospital.

Lung: Chest X-ray, ABGs (serial and with O2 challenge), sputum culture with gram stain, lung/chest measurements as necessary, bronchoscopy and pulmonary consult as necessary.

Liver: Liver enzymes (AST/SGOT, ALT/SGPT, GGT, LDH, alkaline phosphatase), total and direct bilirubin, PT, PTT, INR, platelet count, ABO-A sub-typing, albumin and total protein.

Pancreas: Serum amylase, serum lipase, blood glucose.

Kidney: Urinalysis, creatinine, blood urea nitrogen (BUN), and creatinine clearance as necessary.

Intestine: As requested by transplant center.

Documents all hematology, chemistry, microbiology, and coagulation laboratory results for the current hospitalization.
In Our Members Words . . .  

Read comments from our members and learn how NATCO meets the needs of both new and seasoned members.

**2009 Annual Meeting Attendees**
“For my first conference, as a new member, I was very impressed with the robust content and quality of the presentations.”

“In my sixteen years as a certified transplant coordinator, I continue to be amazed that year after year, the NATCO Annual Meeting provides new information and exciting opportunities for networking and professional growth and development.”

**NATCO’s Introductory Course**  
(Held in June & November each Year)

“I’m not sure anyone could provide a better organized and informative overall educational program for new coordinators. Well worth every penny and any time spent at this program.”

**Membership**

“Membership is made up of many different areas in transplant. Excellent educational programs.”

“Only professional organization that helps to meet the needs of all professionals in transplantation and organ recovery.”

**NATCO, THE ORGANIZATION FOR TRANSPLANT PROFESSIONALS**

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Fax: 913-895-4652  
E-mail: natco-info@goamp.com  
Website: www.natco1.org

NATCO, The Organization for Transplant Professionals offers a great variety of opportunities for professionals to get involved in the organization and community. The following information provides one example of a pathway for involvement with the organization, however your personal journey may differ. Whichever path you choose, the NATCO Board of Directors would like to encourage you to

Get Involved in YOUR Organization!”
NATCO Involvement Pathway—A Guide to Participation in YOUR Organization

Join NATCO
Benefits:
- Education & CE Opportunities:
  - Introductory
  - Intermediate
  - Advanced
  - Workshop
  - Webinars
  - Online Education
- Professional Core Competencies
- Publications
  - Progress in Transplantation Journal
  - In Touch, Quarterly newsletter
- Legislative Representation in

Join a NATCO Committee
Application Available on the Website
Committees:
- General
- Research
- Ethics
- Nominations & Elections
- Procurement
  - Procurement
  - Tissue
  - Family Care
  - Hospital Development
- Clinical
  - Heart-Lung
  - Kidney-Pancreas
  - Liver-Bowel
  - Living Donor

Get Involved in the National Scene
- Vote in NATCO Elections
- Participate in Online Surveys
- Read National Affairs Updates

Attend NATCO Introductory Course
Intense 5-day Course for NEW Transplant and Procurement Coordinators who have Completed Orientation

ABTC Certification
American Board for Transplant Certification
Examinations Available:
- Certified Clinical Transplant Certification (CCTC)
- Certified Procurement Transplant Certification (CPTC)
- Certified Transplant Preservationist (CTP)
- Certified Clinical Transplant Nurse (CCTN)

Certification Study Resources:
- Online Review Courses
- NATCO Core Competencies
- NATCO Textbook: A Clinician’s Guide to Donation and Transplantation

NATCO Annual Educational Opportunities
Annual Meeting
- Obtain up to 22 CEPTCs and Nursing Credits
- Pre-Conference Workshops
- Specialized Educational Tracks
- Hospital Development Course
- New Member/Attendee Reception
- Speaking Opportunities
- Present Abstracts/Case Studies
- Annual Business Meeting
- Networking Opportunities with Colleagues

Symposium for the Advanced Transplant Professional (SATP)
- Designed for Transplant Professionals with More than Three (3) Years of Experience
- Obtain up to 17 CEPTCs and Nursing Credits
- Joint Meeting with American Society of Transplant Surgeons
- Speaking Opportunities
- Networking Opportunities with colleagues and surgeons
Providing comprehensive education, training and networking opportunities for all transplant professionals for 36 years

Vision: That there be a better quality of life for people with end-stage organ and tissue failure...and a respect for those who shared.

Mission: To support, develop, and advance the knowledge and practice of its members and to influence the effectiveness, quality, and integrity of donation and transplantation.

NATCO’s History
• Formed in 1976
  – First meeting: New York, 1976
  – 25 Clinical Coordinators
  – Goal: Meet transplant coordinators’ need for a high quality, comprehensive approach to education
• Today: NATCO is the largest membership association for transplant, procurement, and HD professionals
  – Over 2,000 active members from 7 countries
    • Expanding membership through focus groups for advanced practice clinicians, transplant pharmacists and family care/consent specialists

NATCO’s Purpose
• Encourage and promote research in all transplantation specialty areas
• Provide a forum to present research findings, educate transplant professionals, and exchange ideas
• Promote the concept of equitable access for all patients seeking organ and tissue replacement
• Positively influence transplantation by:
  – Acknowledging and respecting the donor family
  – Promoting the benefits of donation
  – Facilitating the process of transplantation
  – Facilitating donor management guidelines, protocols & research
  – Facilitating the process of clinical transplantation

Educational Accomplishments
• Fall 2006 - Published NATCO’s first textbook for the transplant and procurement practitioner, *A Clinician’s Guide to Donation & Transplantation*
• Provide 4 Ps of HD® to train hospital development staff
  • Revised format in June 2011
• Exploring offering on-line education programs to accompany the Introductory Education Course
• CPTC, CCTC and CTP E-learning Review Courses
• Ongoing educational needs assessment & addition of educational offerings at Annual Meeting
• Symposium for the Advanced Transplant Professional
  • held in conjunction with ASTS
• E-learning Center – Presentations available 24/7
• Laerdal Simulated Mannequin purchased and adding additional Donor Management skills at meetings and OPOs

• NATCO legislative affairs in Washington - meet with key legislators regarding transplantation and donation legislation
• Supporting the HRSA Initiatives
• Published position statements:
  • Donation after Cardiac Death
  • Federal Appropriations
  • Intended Recipient Donation and Paired Live Kidney Donation
  • Living Donor Health Care Coverage, Insurability, and Follow-Up
  • Medicare Coverage for Immunosuppressive Drugs
  • Organ Tourism
• Testified at the Advisory Council on Organ Transplantation (ACOT) meeting regarding living donor insurability
• Two seats on OPTN/UNOS Board of Directors

Patron Saints of Medicine
Cosmos & Damian (285 - 305 A.D.)
1940s Skin Grafting for World War II Burned Soldiers
1952 Stocker 1st Cornea Transplant
1950s Bone and Tendon Transplant as Polio Treatment
1960s Bone Marrow Transplantation Development

1901 Landsteiner Discovered RBC Agglutins, leading to ABO Typing
1952 Dausset (Paris) Identification Antigen HLA-2
1961 Azathioprine 1962 Steroids added
1978 Hamburger (Paris) Identified DR Antigen
1990s Cyclosporine

1940s Medawar (Edinburgh) Identification of Immune Origin of Rejection in Skin Grafting
1958 Total Lymphoid Irradiation
1960s Tissue Typing & Donor Recipient Matching
1976 Cyclosporine

1968 Uniform Anatomical Gift Act
1968-72 State Brain Death Statutes
1973 Medicare Funding of ESRD Program
1980 Uniform Determination of Death Act
1984 National Organ Transplant Act (NOTA)
1980s State Required Request Laws
1986 Omnibus Budget Reconciliation Act (OBRA)
1988 Joint Commission For Accreditation of Healthcare Organizations (JCAHO) Standards for Organ Donation
1998 Medicare & Medicaid Hospital Conditions of Participation for Identification of Potential Organ, Tissue & Eye Donors (CoP)
2007 Revision to UAGA

1938 Carrel and Lindbergh: First Renal Perfusion Machine
1967 Belzer: Kidney Preservation with Continuous Machine Perfusion
1969 Collins: Development of Cold Storage Preservation Fluid
1984 Belzer: Development of UW Solution - Prolonged Cold Storage Capability
Late 1990s Resurgence of Continuous Hypothermic Pulsatile Machine Perfusion
2000 Investigation of Warm Pulsatile Perfusion and Oxygenation Membranes

• Division of Transplantation (DoT)
  – OPTN/UNOS
  – SRTR [URREA]
  – National Bone Marrow Donor Registry [NMDP] Contract
  – Coordination of Organ and Tissue Donor Activities including Secretary’s Initiative
    • Collaborative

Office of the Secretary
Kathleen Sebelius

Centers for Medicare and Medicaid Services (CMS)
Donald Beseck, M.D.

Health Resources and Services Administration
Mary K. Wanner, Ph.D., RN

Other HHS Agencies
National Institutes of Health
Food & Drug Administration
Centers for Disease Control & Prevention
Other agencies
OPTN Final Rule [42 CFR Part 121]
- Effective March 16, 2000
- OPTN Board configuration
- OPTN Membership requirements
- OPTN Policies
- Designated transplant program requirements
- Reviews, evaluation and enforcement
- Data collection and reporting
- ACOT

Organ Allocation Policy
- Based on sound medical judgment
- Achieve best use of donated organs
- Specific for each organ type
- Avoids wastage of organs
- Reviewed periodically and revised as appropriate
- Procedures to promote compliance
- Not based on candidates’ residence or place of listing to the extent feasible

CMS makes nation-wide organ coverage determinations based on analysis of whether the procedure is ‘reasonable and necessary’
- 2001 Adult Liver (HCC – restricted)
- 2000 Intestine
- 1999 Adult Liver (Hep B)
- 1999 Pancreas (SPK and PAK)
- 1996 Adult Liver (excluding Hep B and malignancies)
- 1995 Lung & Heart/Lung
- 1991 Adult Liver
- 1987 Heart
- 1984 Pediatric Liver
- 1976 Kidney – required by statute
- 1972 Kidney – covered under ESRD Program

OPTN/SRTR's most important functions
- Donor organ recipient matching process
- Policy development and its impact on organ allocated

- OPTN committees evolve policy, seek public comment & submit to OPTN Board for approval. OPTN submits policies to HRSA. May seek additional public comments.
- Policies are submitted to ACOT for review & submitted for approval of Secretary. Secretary may send back to OPTN for additional work.

Transplant Centers and OPOs must be certified by CMS to receive reimbursement via Medicare

Regulations defining certification standards are published in the Federal Register
Procurement Coordinators

So, what do they do anyway?

NATCO, The Organization for Transplant Professionals
Introductory Education Course

Evolution of Organ Procurement Organizations

- Organ Procurement Organizations (OPOs) are federally designated, not-for-profit organizations with specific service areas
- In 1989 HCFA (now CMS) mandated that all hospitals must have a Memorandum of Understanding with their designated OPO
- OPO’s provide the link between the donor family and the transplant community

Role of The OPO

- OPO’s not only provide organs for transplantation, but also provide primary support and follow-up to the organ and tissue donor family
  - Great pride is taken in this level of support for the donor family
  - Letter writing and communication is facilitated through the OPO, and is a vital element of the ongoing growth of organ and tissue donation
  - Donor Recognition Ceremony
  - Donor Support Group

Role of the Procurement Coordinator

- Maintain 24/7/365 on-call schedule for all potential organ donor referrals
- Participate in physician and nursing education for the OPO, with hospital staff
- Provide on site evaluation of potential organ donors & support to nursing/medical staff
- Provide family support through the consent discussion process & assure informed consent
- Provide hospital and family follow-up after the donation process

Procurement Coordinator Role

- During the referral:
  - Provide on-site evaluation of medical course, past medical and social history
  - Play detective...facilitate necessary neurological evaluations and documentation
  - Check brain death declaration documentation
  - Meet with family for consent and history questionnaire
  - Report relevant findings to organ placement team, or directly to the potential recipient center
  - Provide support to all departments involved in the donation
Obtaining Consent

- Elements of Consent
  - Legal Next of Kin? (easy right?)
  - Understanding of brain death
  - Education on organ and tissue potential
  - Medical / Social history
  - Complete documentation
  - Provide family support, assure hospital resources are being utilized

Operating Room

- The Procurement Coordinator manages the patient through the entire donation process
- Once the O.R. Begins, the Anesthesiologist typically takes over hemodynamic maintenance
- Procurement Coordinator will facilitate communication to recipient centers
- Also sets up backtable, runs flush and preservation protocols, packages the organs
- Following the organ recovery the Coordinator details the events of the O.R. and the anatomy of each recovered organ & provides copies of all records & specimens to transplant centers

Basic Rules of Allocation

- I thought we could spend a few hours talking about organ allocation...
- Ok...Ok...Local then Regional then National
- ABO compatible
- Sickest then to least sick...

O.R.

- At the conclusion of the OR, the Coordinator will confirm transportation arrangements for the teams and recovered organs (don’t leave them at the airport!)
- Post-mortem care is also performed with the OR staff
  - Vitaly important step in the process
- Final communication to the OR staff and security and typically a visit back to the ICU
- Get home safely!

Allocation of Donated Organs

- Process is ABO, size, time waiting, HLA, and geographically based
- New ABO confirmation
- Coordinator enters the data into the UNOS system and the algorithms for allocation prints the list for each organ
- We call you...and well, you know the rest!
- Arrangements are made for transportation and agreement is made for O.R. time
- We arrange transportation in most cases

Post - Donation

- AOPO requires facilitation of bereavement services for donor families
  - Routine activity includes follow-up letters to the family and all staff involved in the donation
  - Most OPO’s require on-site, 1:1, follow-up as soon as possible post-donation at the hospital to OR, ICU and sometimes to ER
  - Many OPO’s continue to support families with cards, letters at various intervals
  - Many times continue to response to condition updates on recipients & requests for information
Donation after Cardiac Death
An Introductory Course for the NEW Transplant and Procurement Professional
Shannon M Kaminski RN, CPTC Supervisor, Transplant Coordinator Services
Gift of Life Donor Program Philadelphia, PA
Tempe Mission Palms Hotel and Conference Center
Tempe, Arizona

INTENT
What do you intend to take away from this session?

Organ Donation From a Deceased Donor Can Occur In Two Ways:

Donation after Brain Death
Procedure whereby organs are surgically recovered following the determination of death utilizing neurological criteria. Circulation is intact at the time of organ recovery.

Donation After Cardiac Death (DCD)
(formerly known as Non-Heartbeating Donation (NHBD)
Procedure whereby organs are surgically recovered following the determination of death, by neurological or cardiopulmonary criteria, in the absence of spontaneous circulation.

United States Waiting List
Total Candidates
February 2012*

<table>
<thead>
<tr>
<th>Organ</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kidney</td>
<td>90,883</td>
</tr>
<tr>
<td>Heart</td>
<td>3,125</td>
</tr>
<tr>
<td>Lung</td>
<td>1,685</td>
</tr>
<tr>
<td>Kidney/Pancreas</td>
<td>2,128</td>
</tr>
<tr>
<td>Pancreas</td>
<td>1,315</td>
</tr>
<tr>
<td>Heart/Lung</td>
<td>60</td>
</tr>
<tr>
<td>Intestine</td>
<td>281</td>
</tr>
</tbody>
</table>

112,905 TOTAL WAITING

Society of Critical Care Medicine
Critical Care Medicine 2001 Vol. 29, No 9
General Recommendations

- DCD is medically acceptable and ethical provided informed consent is obtained from patient or designee
- Informed consent is ethical cornerstone...Special training required for those obtaining consent due to complexity
- Death must be certified using standardized, objective, and auditable criteria and must follow state law
- It is ethically reasonable for DCD to occur with pediatric patients
- If, in the process of delivering high quality end-of-life care, organ donation is possible then the professional should help enable that outcome
Institute Of Medicine
Examines policy matters regarding public health and advises the federal government

Conducted (2) studies at the request of the Department of Health and Human Services:
→ 1997 Report:
  Non-heartbeating Organ Transplantation: Medical and Ethical Issues in Procurement
→ 1999 Report:
  Non-heartbeating Organ Transplantation II
  Issues in Dissemination

Institute of Medicine
Summary of Recommendations 1997

1. Policies and Oversight
   Protocols are Public Documents
2. Medical Intervention/Ethics
   Use of Anticoagulants and Premortem Cannulation on Case by Case Basis
3. Conflicts of Interest
   Separate Roles/Responsibilities of Care Giving and Transplant Teams
4. Determination of Death
   Controlled - (cessation of cardiac fx for 5 minutes by EKG and heart tones)
   Uncontrolled - (no recommendations; up to local medical experts)
5. Families
   Fully informed of all Procedures and Options (including attending the death of their loved one)

Institute of Medicine
Summary of Recommendations 1999

1. All OPO’s should explore the option of NHBD, in cooperation with local hospital’s, health care professionals, and communities
2. Decision to withdrawal life-sustaining treatment should be independent
3. Observational studies should be undertaken after cessation of cardiopulmonary death
4. Care at end-of-life should focus on the family
5. Efforts undertaken to develop voluntary consensus on practice and protocols
6. Adequate resources must be provided
7. Research should be undertaken to evaluate impact on families, care providers and the public

End of Life Care in the Critical Care Setting

→ 90% who die in the ICU do so after the decision to limit therapy
• Process of withdrawal is variable
→ Withholding or withdrawing medical interventions usually involves detailed and complex conversations with patients’ families (Curtis et al Critical Care Medicine 2001 Vol 29, No. 2)
→ Patients and families do not suddenly switch from the hope for survival and cure to the acceptance of death and pursuit of comfort. The process happens gradually. (Truog et al Critical Care Medicine 2001 Vol 29, No.12)
→ Ethical, Legal, Economic, and Cultural considerations must be understood

DCD Clinical Considerations: Family Discussion

Discussion about withdrawal of care and organ donation are independent and separate

Considerations Regarding Consent
• If it appears that the patient may fulfill brain death criteria, OPO should consult with care team and then family to determine if an extended period of time is granted (IBD vs DCD) Typically between 12 – 24 hours
• Discuss DCD evaluation process
• Discuss Heparin / Vasodilator administration
• Accommodate where possible the family’s request to be present at the time of withdrawal
• Patient may not arrest within required time frame for donation
• Review re-location plan

It is often helpful that the family and care-giving team discuss expectations surrounding comfort care plan prior to the withdrawal of support to avoid perception issues

Nationwide Growth In Donation after Cardiac Death

2010 vs. 1997
1,104% Increase

In 2010, DCD donors provided 1,797 life-saving organ transplants

*Source: Based on OPTN data as of May 4, 2011 for cases through December 31, 2010.

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**DCD Clinical Considerations: Medical Management**

- Medical management should be done in partnership with care-giving team
- Do-Not-Resuscitate (DNR) status should be reviewed
- Patients should continue to receive “quality care” and be managed to maintain physiologic homeostasis
- If appropriate, consider obtaining all necessary blood for transplant purposes and administer Heparin and/or Vasoilator if consented for and indicated prior to the transfer of the patient for withdrawal
- Any invasive procedure that would routinely require hospital consent should be consented separately

**Patient Evaluation for DCD Suitability**

**Respiratory Assessment**

- Respiratory Assessment may be performed at different times during the evaluation process based upon patient's condition, and the family's and CGT's decision making process
- Respiratory Assessment should **not** be performed in certain situations, examples are:
  - Profound hemodynamic instability
  - Severe pulmonary injury (i.e. ARDS)
  - Patient actively receiving sedation
  - High level spinal cord injury
  - Significant dependence on maximal ventilatory support
  - Complete dependence on some type of mechanical device (i.e. ECMO, BiVAD, LVAD, RVAD)
- Other factors to take into consideration, which cannot be driven by the OPO / Transplant Team, are comfort care administration and airway removal

**DCD Clinical Considerations: Communication**

Collaboration between care-giving team members, OPO professionals, and transplant personnel **is critical** for the success of the DCD process

Essential team members who should have a comprehensive understanding of the goals and plan of care surrounding DCD process:

- Attending M.D.
- Pronouncing M.D.
- Primary Nurse
- Respiratory Therapist
- Surgical Recovery Staff
- Anesthesiologist / CRNA
- Ancillary Staff (Social Work / Chaplain)

**Communicate by Design rather than Default**
DCD Clinical Considerations:
**Attending Physician’s Role**
- Identification / referral of potential DCD candidates
- Approval / assistance with respiratory drive assessment
- Partnership with medical management
- Diagnostic and laboratory testing
- Approval for invasive procedures only if necessary
- Approval for medication administration that is not typically given in the care of the dying patient
- Identify a pronouncing M.D.
- Withdrawal of support plan remain in OR (location / comfort care / extubation)
- Re-location plan

DCD Clinical Considerations:
**Primary Nurse**
- Review plan of care and donor management guidelines
- Review documentation requirements
- Ensure that all medications (i.e. comfort care, Heparin, etc.) will be available
- If possible accompany the patient to the O.R./remain present
- Administer comfort care medications as directed by the physician or hospital approved pre-determined pathway
- Review family support plan
- Review re-location plan

DCD Clinical Considerations:
**Primary Nurse and Pronouncing Physician:**
- Review plan of care and donor management
- Review documentation requirements
- Ensure that all medications (i.e. comfort care) will be available
- If possible accompany the patient to the O.R. and remain with the patient
- Review family support plan
- Review Re-location plan

**Pronouncing M.D. (if not the same as the Attending M.D.)**
- Facilitate a discussion with the Attending M.D.
- Ensure that orders have been written by the Attending M.D. for how he/she would like support withdrawn
- Discuss family needs and their end-of-life goals
- Confirm that the Pronouncing M.D. needs to be present the entire time

**Anesthesiologist**
- Care of the patient **should not** be transferred to anesthesiologist in most situations
- Care should only be transferred when the anesthesiologist has had palliative care training and would be willing to assist with withdrawal of support
- Anesthesiologist should be provided the courtesy of being informed of the case and educated on the process

DCD Clinical Considerations:
**Pronouncing Physician and Anesthesiologist:**
- Facilitate a discussion with the Attending M.D.
- Ensure that orders have been written by the Attending M.D. for how he/she would like support withdrawn
- Discuss family needs and their end-of-life goals
- Confirm that the Pronouncing M.D. needs to remain in the OR the entire time

**Organ Allocation**
- DCD organs should be allocated per UNOS or local governing body guidelines
- All organs, including thoracic organs (if the patient is an appropriate candidate) should be attempted to be allocated
- Efforts should be made to expedite testing such as tissue typing to reduce cold ischemic time

**Family in attendance at the withdrawal of support**
- Determine who and how many people will be attending the withdrawal
- Communicate the process
- Determine if the family has any special requirements
- Review prepping and draping
- Describe each persons roles…...If the pronouncing physician is different from the attending make sure you introduce both the physician to the family
- Make sure the instrumentation is reviewed by the staff and recovery team and then cover with sterile drapes and back away from O.R. stretcher. Consider a blockade
- Prepare room for family to go to following the death
- Determine how long the family is going to remain at the hospital following the death
- Post a sign in the O.R. that a family is present!
DCD Clinical Considerations:
Withdrawal of Support & Pronouncement of Death
- Withdrawal of care should be guided by the attending physician or his/her designee
- Comfort care should be administered as needed as determined by the physician overseeing the withdrawal or by hospital approved pre-determined pathway
- Physician pronounces death the way they would normally
  - (Canadian Council for Donation and Transplantation recommend death be determined by two physicians)
  - Death is determined by attending physician or his/her designee
  - Pronouncing physician CANNOT be associated with the transplant team
- Transplant team is NOT permitted in OR until death has been determined
- IOM guidelines are followed (5 min. waiting period)
Note: In the event death does not occur patient will be return to pre-determined area and comfort care will be continued

DCD Clinical Considerations:
Transplant Surgeon and Associated Staff
- Review all pertinent paperwork
- Review donor admission and clinical course
- Review withdrawal and pronouncement process
- Review families presence during the withdrawal
- Review if prepping and draping will occur before or after pronouncement
- Identify who will be doing pronouncement
- Introduce hospital team to recovery team
- Review all instrumentation
- Determine if it is necessary to open the chest
- Identify holding area where recovery team will wait
- Review that patient is to have no invasive procedures (i.e. staples, towel clips, etc.)
- Identify person who will be updating surgeon regarding information pertaining to the withdrawal
- Communicate pronouncement time and the time first incision should be made

Hospital Profile
- Comprehensive medical center located in Bucks County Pennsylvania
- 366-bed licensed beds
- Operates the only state-accredited Level II Regional Trauma Center and the only Pediatric Emergency Care Center in Bucks County
- > 60,000 Emergency Service and Trauma Center cases in 2008

DCD Clinical Considerations:
Surgical Recovery
- Transplant team initiates surgical recovery via abdominal aortic approach
  - Femoral cannulas can be utilized if necessary, however may pose additional technical, and ethical challenges
- Organs preserved with UW or HTK solution and packaged using simple cold storage
- Pulsatile preservation is utilized in some cases based on warm ischemic time and/or pre-existing comorbidities

Initial Referral / Clinical Presentation
1/29/2009 @ 11:32 hrs
- Referred to Gift of Life Donor Program (GLDP)
- Police Officer
- Active Trauma Code with resuscitative efforts by Trauma/Critical Care
- Family on way to hospital
- Recovery surgeon notified by coordinator while enroute to hospital
On Site Evaluation

1/29/2009

- Coordinator arrived @ 12:35 hrs in ER
- Resuscitative Efforts stopped @ 12:28 hrs with pronouncement of death
- Wife secluded with Police Department
- Trauma Bay guarded by Police Department
- Trauma Attending notified of OPO arrival

Organizing The Pre-Recovery Phase

- Transported to OR @ 13:00 hrs
- Prepping and draping completed with chest compressions continuing
- Anesthesia d/c BVM, placed on ventilator
- OPO Administrator indicated delay for recovery surgeon and perfusionist due to traffic and limited availability of helicopter transport
- Additional 20,000 units Heparin given at 14:00 hrs

Preserving The Opportunity With Collaboration

- OPO Administrator notified, mobilization of transplant surgeon and perfusionist
- Re-established chest compressions and oxygenation via ETT/BVM @ 12:45 hrs
- Operating Room Notified
- Medical Examiner Contacted
- Necessary Labs Secured (Serology, HLA, terminal BUN/Creatinine, ABG)
- 30,000 units Heparin administered @ 12:55 hrs
- Cold saline initiated through femoral triple lumen catheter

Recovery

- Incision @ 14:13 hrs
- Cross Clamp @ 14:22 hrs
- Kidneys Recovered En-bloc @ 14:58 hrs
- Second OPO coordinator arrived @ 15:00 hrs, escorted to home of police officer
- Heart Recovered for valves @ 15:07 hrs
- Written consent and medical social history completed @ 15:45 hrs

Providing the Opportunity A Family Driven Process

<table>
<thead>
<tr>
<th>What We Want</th>
<th>Hospital Staff Perception</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increase Organ Donation Opportunities</td>
<td>No donation opportunity</td>
</tr>
</tbody>
</table>

Steps Taken to Achieve Goal:

- Clear communication that donation opportunities still existed
- That providing this opportunity is not adding to the emotional stress of the family and fellow police officers
- Being aware that the police officer was well know to emergency room staff and trauma attending
- The wife indicated “we would want to save someone else today”

Working with HCT (Health Care Team) to understand the re-initiation of chest compressions and oxygenation was for the purpose of organ recovery and not resuscitation

Kidney Recovery Data

Warm Ischemic Time
(Time from initial onset of injury)
180 minutes

Biopsy Results
- Right Kidney 9 glomeruli seen with none sclerosed
- Left Kidney 23 glomeruli seen with none sclerosed

Pulsatile Preservation Results after 9.5 hours

Right Kidney:
- Initial flow of 49 cc/min and resistance of 0.57
- Final flow of 135 cc/min and resistance of 0.22

Left Kidney:
- Initial flow of 50 cc/min and resistance of 0.56
- Final flow of 135 cc/min and resistance of 0.22
Outcomes

- **Right Kidney**: 61 year old female, had initial ATN, currently with normal function and creatinine of 1.5
- **Left Kidney**: Family directed donation to 40 year old male who served with donor in the military, had immediate function with current creatinine of 1.0
- **Heart Valves**

---

**DCD Donors Recovered in the U.S.**

2010: 929
2009: 842
2008: 668
2007: 564
2006: 444
2005: 393
2004: 268
2003: 198
2002: 168
2001: 117
2000: 87
1999: 75
1998: 78
1997: 70
1996: 64
1995: 64

(n=6,215)

---

**Kaplan-Meier Patient Survival**

6,047 DCD Kidney Transplants in the U.S.
Transplant Date: 1/1/2006 – 6/30/2010

---

**DCD Organs Transplanted in the U.S.**

2010: kidneys (1,299) / lungs (267)
2009: kidneys (1,311) / lungs (280)
2008: kidneys (1,278) / lungs (129)
2007: kidneys (1,086) / lungs (297)
2006: kidneys (1,086) / lungs (192)
2005: kidneys (954) / lungs (88)
2004: 897
2003: 749
2002: 741
2001: 681
2000: 562
1999: 599
1998: 697
1997: 712
1996: 706
1995: 743

---

**5.8% of Deceased Donors Recovered 1995 – 2010 Were DCDs**

**Collaborative Goal**

---

**106 DCD Lungs Transplanted in the U.S. 1997 - 2010**

*Source: Based on OPTN data as of 3/18/2011*
6,047 DCD Kidney Transplants in the U.S.
Transplant Date: 1/1/2006 – 6/30/2010

1,752 DCD Liver Transplants in the U.S.
Transplant Date: 1/1/2006 – 6/30/2010

Kaplan-Meier Patient Survival

Kaplan-Meier Graft Survival

Source: Based on OPTN data as of 3/18/2011
Kaplan-Meier Graft Survival
1,752 DCD Liver Transplants in the U.S.
Transplant Date: 1/1/2006 – 6/30/2010

This work was supported in part by Health Resources and Services Administration contract 234-2005-370011C.

The content is the responsibility of the authors alone and does not necessarily reflect the views or policies of the Department of Health and Human Services, nor does mention of trade names, commercial products, or organizations imply endorsement by the U.S. Government.

Compassionate End of Life Care and Organ Donation should not be viewed as a Conflict of Interest ……

End of Life Care
Organ Donation

however as a Confluence of Interest
Understanding OPO Financing

P.J. Geraghty
Director of Organ Recovery Services
Donor Network of Arizona

To stay in business, your revenue must be greater than or equal to your costs

• Regulated by CMS
• Not-for-profit status
• 58 OPOs
  – 51 Independent
  – 7 Hospital based
• Common mission
• Widely variable service area size and population

• Organ Procurement
• Tissue Procurement
• Eye Procurement
• Interest Income
• Grants and Donations (foundations)

Standard Organ Acquisition Charge
- Fee charged to transplant center
- Based on costs of procurement, preservation and distribution of recovered organs (including those worked up but not transplanted)
- Average costs vs. patient specific
- Calculated similarly to DRGs

• Rate controlled by OPO
  - Variables – staff, region
  - Less “standard”
    - Surgeon fees
    - Transportation
    - Services provided

Organ Acquisition Charge (OAC)

- Donor Hospital
- Salaries and benefits
- UNOS Registration
- Hospital Development
- Kidney Surgeon Fees
- Public Relations
- General and Admin
- Preservation
- Import Organ Fees
- Transportation
- Coordination
- Tissue Typing
- Community Education

Typical Breakdown of OPO Costs

- Administrative/General - 20%
- Indirect - 40%
- Direct - 40%

• OAC - Determined by Center for Medicare and Medicaid Services (CMS) intermediary
• CMS – Medicare = #1 payor for kidneys
• OPO – must break even
  - NO profit
  - NO loss
  - Checks/balances – Medicare audits
  - Cost report filed with intermediary

• Expenses directly related to recovery and transportation of organs – (from surgeon fees to ICU pizza)
• Donor hospital charges after consent/death
• Tissue typing
• Organ procurement staff
• Donor hospital discounts/case rates
• Verification of actual charges (AMBR)
• Transportation contracts
• OPO-based point of care testing
• OPO-provided supplies/staff instead of hospital
• OPO recovery facilities

Indirect Costs
• Costs related to maximizing donation
• Hospital development
• Community education
• Professional education
• Marketing initiatives
• Staff salaries
• Supplies
• Anything that cannot be allocated to a specific organ or donor

General Services and Administration
• Costs incurred to manage the operations of the OPO
• Administrative and support staff
• Information systems
• Rent
• Insurance
• Electricity
• Etc.

“Intent to recover”
• Critical step in cost accounting
• “Intent” is determined when entering the OR with the donor
• Organs ruled out intraoperatively count as “intended” and affect the breakdown of charges
• DOCUMENT your INTENTIONS prior to or
Spread costs across all organs recovered with intent to transplant

More organs transplanted per donor =
- more lives saved
- lower acquisition cost

- Quality improvement processes
  - Improved donor management
  - Improved organ placement
  - INCREASE ORGANS PER DONOR!
- Non-traditional staffing
- Research to improve organ viability
- Partnerships with transplant centers

Dynamics of Organ Acquisition Costs

Pressures that Increase Cost
- Expanded donors
  - Higher discard rate
  - More single organ donors
  - More ZERO organ donors
- Resources to increase conversion rate
  - Hospital development
  - Family services
- Communications center improvements
- Broader organ sharing
- Competitive staff salaries and benefits
- Increasing medical costs
- Preservation technologies
- Transplant center demands

Reminders!
- Document expenses extensively
- Obtain itemized receipts
- Sign-in sheets for all participants
- Agendas for every meeting
- INTENT!

Summary
- Who pays for the cost of donation?
- How are expenses distributed?
- What factors influence donation costs?
- What is your role?
NATCO Introductory Education Course

Reimbursement Issues in Transplantation

Lauren Rutledge, Director
Banner Good Samaritan Transplant Center

Market Evolution - Health Care Delivery System

- **Stage 4 - RISK**
  - > 50% Fixed Pricing, Value Competitive
- **Stage 3 -**
  - < 50% Fixed Pricing, Price Competitive
- **Stage 2 -**
  - < 30% Fixed Pricing, Excess Capacity
- **Stage 1 -**
  - Fee - For - Service, < 10% Fixed Pricing

Types of Managed Care

- Medicare
- Diagnosis Related Group (DRG)
- Medicaid
- Fee-for-Service (% charges)
- Commercial Payors (HMO, PPO, POS)
- Medical Groups
- Capitation (IPOs)
- Cash

What is Managed Care?

- Describes Various Discounted Fee Arrangements & Contract Negotiations for the Delivery of Health Care Services
- Utilizes Case Management Principles to Control Costs & to Monitor Quality of Services Provided

Transplant Contracting

*Rates Currently Negotiated*

- **Fee - for - Service** (Discount off of Charges – 80%)
- **Case Rate** (Fixed Payment for a Specific Episode of Care)
- **Global Payment** (Fixed payment includes physicians)
Transplant Contracting

Global Rates

- Fixed Payment for Care Provided during Specific Timeframe
  - Transplant Admission Plus 90 Days ($100,000)
  - Evaluation Through One Year Post-Transplant ($150,000)

Phases of Transplant Care

What Costs are Included?

- Transplant Admission
  - Cadaveric or Living Acquisition Charges
  - Inpatient Stay
  - Outpatient Follow-Up & Readmissions (Global)

- Post-Transplant Follow-Up
  - Onsite Outpatient Clinic
  - Telemedicine or Outreach Clinics
  - Readmissions
  - Home Health

Phases of Transplant Care

Contract Negotiations

- Phases or Stages
  - Evaluation Services
  - Pre-Transplant (Waiting/ Maintenance)
  - Transplant Admission
  - Post-Transplant Follow-Up

Phases of Transplant Care

How Payors Reimburse

- Pre & Post Transplant Care
  - General Services Agreement - Hospital
  - Physician Fee Schedule
  - Can be included in a Global Contract

- Transplant Admission
  - Hospital & Physician Payment Together
  - Case Rate with Stop Loss Protection
  - Global for Admission Plus 90 Days

Contract Exclusions

- Prescriptions
  - Non-Transplant Medications (Pre-Transplant)
  - All Discharge & Follow-Up Medications (contract dependent)

- Services not Provided by Transplant MDs
- Services not Provided by Transplant Center
- New Technologies
  - New Devices, Medications, Surgeries
What Impacts Transplant Costs?
*Doesn’t Mean More Payment!*

- OPO Increases Acquisition Fees
- Uncoordinated Delivery of Services
- Patient Case Mix Increases
- New Clinical Protocols Occur
- New Technology – New Protocols
- Research Items now Part of Protocol
- Payor Case Mix Changes

Organization Philosophy
*Taking Risks*

- Ability to Absorb Non-Covered Costs
- Community Service vs Bottom Line
- Efficiency & Quality
- Evolution
  - Internal Changes
  - External Changes

Transplant Contracts

- Will Rates Cover Costs?
- What Volume Will Occur?
- What Type of Patients Will be Directed?
- Contract Implementation
  - *Can you provide what you agreed to?*
  - Internal Support Systems in Place?
  - Communication Protocols Established?
  - Have both financial and clinical reviewed the contract with the negotiator?

Delivery of Transplant Care
*Key Indicators*

- Quality
  - UNOS Case Mix Data
  - Patient & Graft Survivals (Risk Adjusted)
  - Volume
- Cost Effectiveness
  - Length of Stay & # of Readmissions
  - Carepaths
    - Concurrent Review
    - Trends

Transplant Center Assessment
*Organization Make-up*

- Team Cohesiveness
- Data Systems (Accessibility)
- Quality Management
  - Review Clinical Outcomes
  - Review Revenue & Costs
- Latest Technology
- Clinical Research

"The transplant went okay, but your insurance company is rejecting the bill."
Transplant Center Assessment

Service & Efficiencies

- **Service**
  - Patient Satisfaction
  - Referring MD Satisfaction
  - Case Manager & Payor Satisfaction

- **Efficiencies**
  - Clear, Ongoing Communication
  - Transplant Team & Key Departments
  - Patient, Referring Physician, Payor

---

Standard Acquisition Charge or Kidney Acquisition Cost Center

- Patient is evaluated and all bills for evaluation go to the KACC
- Patient is listed and listing fees go to SAC
- Annual re-evaluation goes to KACC
- Monthly PRA’S go to KACC
- % of salaries of staff, space, living donor stays are also included
- These dollars are aggregated into an amount. For example, we will use the figure $22,000.

---

Efficient & Timely Contracts

**Designated Team**

- Empowered Contract Negotiator
  - Hospital & Physician
- Front End Financial Coordination
  - Authorizations, Benefits, Exclusions
  - Identify Real Payor
- Dedicated Billing Coordinators
  - Hospital & Physician
- Accurate, Timely Clinical & Financial Data
  - Hospital & Physician

---

SAC continued

- Then look at the OPO cost
- The OPO has a OAC charge made up of staff, supplies, space, education, donor hospital bills, all donor testing, and organ transportation.
- These dollars are aggregated into an amount. For our example, we will say $24,000

---

Successful Contracting

**Transplant Centers**

- Maintains Volume & Revenue
- Markets Hospital & Physicians Effectively
- Becomes Key Component of Center’s Business Development Strategies
- Keeps Current with Clinical & Financial Trends (Costs & New Services)
- Represents Patients’ & Centers’ Best Interests

---

SAC continued

- At time of transplant a charge is placed on the patients bills for $46,000 which covers cost for both the Transplant Center and the OPO.
So how does this get paid?

- Medicare - the DRG for kidney transplant is $20,600 so add the $46,000 SAC (through MCCR) and the facility is paid $66,000. This does not include physicians; they bill on their own.
- General Services Agreement - % of charges, for example 80%. This does not include physicians.
- Global contract-hospital and physicians rolled into one fee.

What about other organs?

- Insurance is billed for the evaluation.
- Patient is listed and listing fees go to OAC.
- Annual re-evaluation goes to OAC.
- % of salaries of staff, space, living donor stays are also included.
- The OPO has the same costs as above excluding transportation which the center has to pay.
- The DRG for the transplant and OAC from the OPO are billed with kidneys on the UB, and physicians bill on their own.

Global fees

- Doctors and hospital stay in one payment
- Global rates vary widely from center to center
- Why do we do it?
- We must stay competitive, get contracts and to survive in the “business” of transplantation.
Introduction to Transplant Ethics

Courtenay R. Bruce, JD, MA
Assistant Professor of Medicine and Medical Ethics
Baylor College of Medicine
Coordinator, Ethics Consultation Service, The Methodist Hospital System

Transplant Medicine: A Profession
- A profession because it is a vocation requiring
  - Specialized knowledge in a field
  - High quality work
  - High standard of professional ethics
- Society puts their trust in professionals with requisite skills and education
  - This trust means you have obligations to society

Outline
- Part I: The Organ Shortage
  - Why Should We Care About Ethics?
  - Ethical Theories
- Part II: Donor Organs
  - Incentives
  - Informed Consent
- Part III: Recipients
  - Prisoners
  - Split Livers
  - Organ Tourism
- Part IV: Practical Considerations for Coordinators
  - Patient Selection Process
  - Dealing with difficult patients
  - Enhancing Communication with Patients and Families

Why Should We Care About Ethics?
- Because of the nature and complexity of transplant medicine ...
  - The Nature of Transplant Medicine
    - It's a profession with professional obligations
    - Unethical behavior can tarnish transplant medicine
  - The Complexity of Transplant Medicine
    - The stakeholders' interests involved ("duality" of interests)
    - The decision making and processes

Transplant Medicine: Stakeholders’ Interests
- A common ethical issue are multiple interests and conflicts between these interests
  - A Conflict of Interest exists when two “goods” are competing against each other for priority
    - Can be tangible or intangible
    - Can be personal or institutional
    - Can be self-interested or altruistic
    - Can conflict among one person and between one person and another
  - Goods: Money, fame, promotion, statistics, patient safety, patient, QoL

Transplant Medicine: Stakeholders’ Interests
- Duality of interests (Conflict)
  - To the patient (donor, recipient, candidate)
- To the transplant program
  - Superior morbidity and mortality statistics
  - Aggressive, innovative (reputation)
  - Volume
- To transplant medicine
  - Stewardship: Responsible planning and management of resources
Conflicts of Interests:
Using Bioethical Principles as a Paradigm
Autonomy: Actions tend to be right insofar as they respect autonomous choices.
- Informed Consent for LD
- Informed Refusal (Extended Criteria Donations)
- Directed donation
- Transparency of processes and allocation rules to enable an informed decision
- Beneficence: Do good
- Nonmaleficence: Do no harm (consider LD)
- Justice: Fair distribution of benefits

Ethical Theories

- Why Appeal to Ethical Theories?
  - The primary ethical dilemmas surrounding organ.txp arise from the shortage of organs recovered.
  - Policies need to be aimed at both increasing donations well as a system that allocates organs in the fairest way possible.
    - Allocations must be based on both efficiency and equity

Ethical Theories: Application to Transplant Policies

- UNOS encourages TCs to consider the following criteria for distributing organs:
  - Medical Need (Utilitarian)
  - Probability of success (Utilitarian)
    - Efficiency Criterion: Concern about maximizing net benefits
    - Time on the Waiting List (Deontological)
  - Equity Criterion: Requires that we pay attention to the patterns of distribution.

Increasing Donation

Part II: Increasing Donations
Strategies to Increase Donation
1st Person Consent

Increasing Donation

- 4 Strategies to increase donation
  - Presumed Consent
  - Mandated Choice
  - Preferred Choice
  - Incentives
    - Give assistance to families of a donor with funeral costs
    - Donate to a charity in the deceased person's name
    - Provide financial or payment incentives
Increasing Donation

- Are the strategies ethically permissible? Ask yourself:
  - Is the process ethically justified?
  - Would it help or harm organ donation?

Presumed Consent

<table>
<thead>
<tr>
<th>Advantages (Proponents)</th>
<th>Disadvantages (Opponents)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Asking for consent is too hard on families</td>
<td>1. Requires people to take action and this unfairly burdens some people.</td>
</tr>
<tr>
<td>2. Burden of communicating objection should be on objectors</td>
<td>2. Individuals do not have a social duty to express an objection</td>
</tr>
<tr>
<td>3. Promotes efficiency</td>
<td>3. False positives</td>
</tr>
<tr>
<td></td>
<td>4. Consent should be positive, not implied</td>
</tr>
</tbody>
</table>

Increasing Donation: Preferred Choice

- Involves the rewarding of organ donors by providing them with a modest but definite recognition, in kind, for their willingness to participate in the system.

- Lifesharers.com: “As long as there is a shortage of organs, it’s not fair to give organs to non-donors when there are donors who need them.”

Increasing Donation: Mandated Choice

<table>
<thead>
<tr>
<th>Advantages (Proponents)</th>
<th>Disadvantages (Opponents)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Eliminates need for family approval</td>
<td>1. The Texas Experiment—Failure</td>
</tr>
<tr>
<td>2. Respects autonomy</td>
<td>2. Coercive</td>
</tr>
<tr>
<td>3. Increase public awareness</td>
<td>3. Lack of public education</td>
</tr>
<tr>
<td>4. Preserve altruistic model</td>
<td>4. Lack of conversation</td>
</tr>
</tbody>
</table>
Increasing Donation: Financial Incentives

- AMA 2002: Called for consideration of pilot studies to measure the effectiveness of incentives on donation rates as well as public perception.
  - 96% of people sold their kidneys to pay off debt
  - 74% still had debt 6 years later
  - 86% reported a deterioration in their health status after donation
  - 79% would not recommend it to others

### Increasing Donation: Financial Incentives

<table>
<thead>
<tr>
<th>Advantages (Proponents)</th>
<th>Disadvantages (Opponents)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Donors/families are the only participants not directly benefiting from the process</td>
<td>1. Donation rates could decrease. Backlash from the current donor pool based on altruistic giving.</td>
</tr>
<tr>
<td>2. Financial incentives are part of medicine</td>
<td>2. Decrease emotional gain for families</td>
</tr>
<tr>
<td>3. Based on concern for patients; argue that opponents reject proposal based on unproved theoretical disadvantages</td>
<td>3. &quot;Organ brokers&quot;, bureaucracy, administrative costs</td>
</tr>
<tr>
<td>4. Implement safeguards</td>
<td>4. Does not address underlying problems</td>
</tr>
<tr>
<td>5. Studies show that half of those surveyed are in favor of some form of compensation (UNOS/KNF and UNOS Ad Hoc Donations Committee)</td>
<td>5. Research needed on: (a) why some families are not asked to donate and (b) why donations do not occur more often when asked.</td>
</tr>
</tbody>
</table>

Financial Incentives: Using Living Organ Donation as a Paradigm

- Compensating donors for expenses they incur as a result of donation (e.g., travel, work)

  1. Source and amount of compensation?
  2. When should it be offered?
  3. How would system be administered?

  High mortality—clear that profit to be gained was more important than the welfare of patients (India)

Increasing Donation

- **Summary/Best Practices:** No incentives. Stick with the altruistic model.
- Altruistic model is based on autonomy of donor.
- Respecting autonomy:
  - Case Study on next slide

Case Example

- Third-year medical student, Mike, is in the midst of his trauma surgery rotation. He rushes to the trauma department after he is paged and learns that his next patient, Justin Lewis, is a 20-year-old male who was in a major automobile accident. According to the EMTs, Justin fell out of a car that was traveling 70 miles per hour and landed on this head. After an extensive emergency room workup, Justin is declared brain dead. Prior to disconnecting him from the ventilator, the ED staff discovers that he has an organ donor card in his wallet. Familiar with the organ donation procedures, Mike calls the organ procurement agency while the attending, Dr. Hardy, tells Justin’s family the news.

  An hour later, Mr. Sterling, a representative from the organ procurement organization arrives at the hospital and introduces himself to the family. Justin’s father tells Mr. Sterling that his son definitely wanted to donate his organs, but Justin’s mother interjects. She is adamantly opposed to anyone’s taking organs out of her son. What should be done?

Adapted from a case found at [www.ensoullmentor.org](http://www.ensoullmentor.org)
Increasing Donation

- "If there is a signed donor card by the decedent, the limited privilege of the next of kin to later get the body for burial is subject to the superior right of the OPO to the body. [By signing the donor card], the decedent donor has already made an effective donation of an asset to the OPO... The next of kin cannot interfere with the donation that has already been made.”

Increasing Organ Donation

- UAGA (2006): “An anatomical gift that is not revoked by the donor before death is irrevocable, [and] does not require the consent or concurrence of any person after the donor’s death.”
- In all 50 states, the OPO is not liable in a civil action for taking an organ without the consent of the next of kin provided they OPO attempts to act in accordance with the UAGA.

Increasing Organ Donation

- The public coroner or the public health officer may donate the organ if no document indicating the donor’s intent can be found and the next of kin is not available within a reasonable amount of time. [Leonard Bucklin; 1987 UAGA]
- Reasonable time: Organ viability [need and efficacy of life support system must be considered]

Living Organ Donor

- Living Related and Nonrelated Organ Donation
  - Informed Consent
  - Harming Donor
  - MatchingDonors.com
  - Solicitation
  - Good Sam Programs

Living Donations: Spectrum of Ethical Complexity

- Living Related Donations (Directed; recipient known to donor)
- Living Unrelated Donations (Directed; recipient known to donor)
- Non-directed Donations (Anonymous)
- Paired and chain donation (Likely no preexisting relationship)

Living Related Organ Donation: Informed Consent

- Informed Consent Requirements
  - Adequate Disclosure of information
    - Diagnosis
    - Nature and purpose of treatment
    - Risk of treatment
    - Treatment alternatives
  - Patient Voluntariness
  - Patient Comprehension of Information
  - Patient capacity for Decision Making
Living Related Organ Donation: Informed Consent

- Can the donor’s decision ever be truly voluntary?
  - “He’s my brother, my sister…”

- On the other hand, is such pressure unique to organ donation?
  - Aaron Spital: “The mere fact that a person feels bound to donate does not render the consent given involuntary.”

Living Related Organ Donation: A Case

- 22 y.o. old Guatemalan woman presents to be a living liver donor for her cousin. She is undocumented and in the U.S. illegally. Her history includes hypertension (resolved) and post-partum depression (resolved). She does not smoke, drink, or exercise. She has a BMI of 30. She is not married, has a baby, and works as a domestic worker. Because she does heavy lifting at work, she will not be able to return to work for 6 weeks post-surgery. Should she be able to donate?

Living Related Organ Donation: Harming the Donor

- When is it not ethically permissible?
  - Example:
    - Both parents of a child who was dying of respiratory failure insisted on donating lobes of their lungs in a desperate attempt to save her life.

- Physicians are obligated to prevent people from making life-threatening sacrifices unless there is a proportionately large chance of success.


Living Related Organ Donation: Informed Consent

- People’s actions are rarely if ever fully autonomous.

- For an action to be autonomous, we should only require a substantial (not complete!) degree of understanding and voluntariness.

- **Summary/Best Practice:** You have an ethical obligation to ensure that the decision is as informed as it possibly can be.

Living Related Organ Donation: Summary

- Informed Consent
  - Internal pressure may exist and that may OK if
    - Informed consent process is as robust as it can be.
    - (Practical suggestions on next slide.)

- Harm
  - It is ethically permissible to harm one individual primarily for the benefit of another if:
    - The individual operated upon derives benefit
    - The procedure helps the individual accomplish a good act
Informed Consent

- Practical Suggestions
  - Give them time to think
  - Interview them alone and with family members (look for coercion)
  - Give prospective donors your contact information to rescind participation
  - Don’t overestimate benefits or underestimate risks
  - Present morbidity and mortality statistics
  - Discuss psychological, financial, and insurance risks

Living, Unrelated Donation

- Shouldn’t donation to a complete stranger be given the highest respect? Beyond “call of duty”
  - Spital argued that it seems illogical to emphasize altruism for living donations and then limit opportunities to act altruistically by confining donation to relatives only.
  - Public attitudes towards LD are quite positive (H. Sadler, A. Spital)

Living, Unrelated Donation

- Donors are usually emotionally involved but genetically unrelated donors (spouses, partners, close friends)
  - Graft survival similar to the five-year survival of transplants from genetically related donors and better than that of cadaveric donation

Good Sam Programs

- An “anonymous” adult makes an altruistic donation to an unidentified recipient
  - The donor cannot “direct” the donation to a specific patient or type of patient (gender, race, religion, etc.)
  - The donation is directed to the institution who then chooses the recipient

Living, Unrelated Donation

- Is it ethically permissible to physically harm one individual (living donor) who is a complete stranger to the recipient? Often, yes.
- It is permissible because:
  - Outcomes from genetically unrelated living donors is excellent at many TCs.
  - Studies: No evidence of psychopathology before donation, or psychological complications or regret after donation. (Sadler)
  - Higher satisfaction because no sense of obligation

Good Sam Programs

- Informed consent process unique
  - What motivates potential donors?
  - What are their conflicts of interests?
  - Do the donors have their own health insurance?
  - Does the donor’s spouse support the decision?
  - What are their motivations?
  - Mental and physical health of potential donor
  - Long-term follow-up
  - Have a cooling off period b/t consent and donation
Good Sam Programs

• Things to address programmatically
  – Are some types of donation too risky?
  – What constitutes an inappropriate donor? What are inappropriate comments?
  – If donor is identified by recipient: Should relationships between donor and recipient be encouraged, tolerated, prohibited if this relationship did not exist beforehand?

Solicitation

• 2004: First transplant through MatchingDonors
  – Recipient sought kidney for 5 years
  – Says he did not pay for the kidney
  – Reimbursed donor for $5000 for expenses.
  – Donor jailed for failure to pay child support.
  – 2005: Donor failed a televised polygraph test

Good Sam Programs

• The potential donor must undergo evaluations
• Protect donors from coercion and undue influence;
• Respect should be given to individual’s autonomous decisions while minimizing her/his exposure to risk;
• Robust informed consent required;
• Safeguards should be followed to assure anonymity between the donor and the candidate;
• Organs must be allocated in an equitable manner according to existing policies; and
• Donor outcomes should be evaluated.

Solicitation

Paired Donations

Matching Donors

• Is the internet an appropriate forum for soliciting organs?
• Potential problems: (a) inequity in organ donation; (b) inability to verify info; (c) lack of psychological screening; (d) How will the websites be held accountable?
**Paired Donations: Benefits**

- Benefits
  - The primary benefit for the recipient is the timely receipt of a healthy organ
  - Increases opportunities for living donation
  - Patients are generally healthier when transplanted
  - Surgical risk remains the same as it would for any other living donation
  - Great way to help those who have a hard time getting a match

**Summary/Best Practices:**

- Real procedural and ethical issues here that are difficult to mitigate
  - Pressure or coercion may be increased. If you withdraw, you let multiple people down.
  - Informed consent process is complex
  - A new relationship is creating through the donation process

**Paired Donation: Problems**

1. Privacy and confidentiality difficult to maintain
2. Donors cannot withdraw
3. Some recipients may decide they cannot ask a potential donor to donate to a stranger
4. A reluctant donor cannot invoke ABO incompatibility as the reason for not proceeding with donation.
5. Psychological benefit for donor more diffuse that direct donation

**Summary of Donation by Living Persons**

- Public trust matters.
  - Safety of donation
  - The integrity of the allocation system
- 2002: A donor died after giving a portion of his liver to his brother.
  - 2000-2001: 395 → 518
  - 2002: 362
  - 2003, 2004: 320

**Paired and Chain Donations: Possible Solutions**

<table>
<thead>
<tr>
<th>Problems</th>
<th>Possible Solutions &amp; Counterarguments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Privacy and confidentiality concerns</td>
<td>1. Cooling off period after donation</td>
</tr>
<tr>
<td>2. Donors cannot withdraw</td>
<td>2. Do the procedures simultaneously</td>
</tr>
<tr>
<td>3. Some recipients may decide they cannot ask</td>
<td>3. Potential recipient should give informed consent before donor undergoes</td>
</tr>
<tr>
<td>a potential donor to donate</td>
<td>screening</td>
</tr>
<tr>
<td>4. A reluctant donor cannot invoke ABO</td>
<td>4. Opportunities can be provided at each stage in the process to disqualify</td>
</tr>
<tr>
<td>incompatibility</td>
<td>themselves on unspecified medical grounds</td>
</tr>
<tr>
<td>5. Psychological benefit more diffuse, less</td>
<td>5. Could the donor experience more benefit knowing he/she helped a stranger</td>
</tr>
<tr>
<td>direct than direct donation</td>
<td>as well as facilitated helping his friend/relative?</td>
</tr>
</tbody>
</table>

**Recipients**

*Part III: Ethical Issues Unique to Organ Recipients*

- Extended Criteria Donations
- Prisoners
- Organ Tourism
- Split Livers
Extended Criteria Donations

- Should patients know that the organ being offered to the prospective recipient is an extended criteria organ?

- What is the harm of providing full information?

- Should the prospective recipient be able to refuse the organ based on this?

Prisoners:
The Story of “Jailhouse Joe”

- CA prison inmate serving 14 years for robbery
- Received a heart transplant while in prison
- Is this OK? Why or why not?

Extended Criteria Donations

- Obligation to provide information to patients about extended criteria donations is based on the assumption that these organs place the patient at a significantly higher risk than that which they previously consented, but...

- Is this true?

- Potential conflict b/t surgeon’s obligation to obtain informed consent and stewardship.

Prisoners:
The Story of “Jailhouse Joe”

- New facts: Is it still OK if you learned that...
  - It cost the taxpayers over $1 million?
  - He died within 11 mo. of transplant?
  - He died, at least in part, because of noncompliance with meds?
  - Because of court rulings about cruel and unusual punishment, inmates are given priority over the 7 million Californians who lack medical insurance?
  - Prospective donors tore up their donor cards in protest?

Extended Criteria Donations

- What should these prospective recipients be told, then?
  - The patient should understand what is not known as much as what is known.
  - The pt. should be told that the surgeon believes that it is reasonable to undergo procedure, even with the uncertainty.
  - That proceeding with surgery is in the patient’s best interest.
  - Talk about it with the patient in advance.

Prisoners:
The Story of “Jailhouse Joe”

- Would you feel differently if you learned that he was in jail for robbery, was released, and robbed again?
- Would you feel any differently if he murdered someone?
- If he were a pedophile?
- What if he was on death row?
Prisoners: The Story of “Jailhouse Joe”

- **Summary/Best Practices:**
  - One’s status as a prisoner does not preclude them from consideration for a txp.
  - However, one’s status as a prisoner may evoke other concerns that are legitimate and can be considered in review (e.g., noncompliance, infectious diseases, psychosocial issues)

Split Livers

- **Summary/Best Practices**
  - Splitting medically suitable livers is ethically appropriate.
  - Patients can refuse an offered organ.
  - Patients should be told about current program practices at time of listing. Info should include: (a) morbidity statistics, (b) experiences with split versus whole liver in the TC where the patient is listed and other TCs.
  - Patients who decline split livers at time of listing should still be offered when one becomes available.
  - No claim of ownership or entitlement.

Split Livers

- If a patient has ascended to the top of the waitlist, should he/she be entitled to receive a whole liver even if the organ could be split to benefit two patients? [Ownership]

- Would you have to work your way down the waitlist to find someone who is agreeable, perhaps losing a viable organ? [Stewardship]

Organ Tourism

- Should physicians be obligated to treat patients who receive an organ overseas?

- Should it be an obligation to treat for emergent care? Follow-up care?

- Must you provide the medical chart to someone who is going overseas for a txp?

Practical Considerations

**Part IV: Practical Considerations for Coordinators**

- **Patient Selection Process**
- **Managing Difficult Patients**
- **Enhancing Communication**
Patient Selection Process

- The Challenge:
  - Each patient is a unique individual, with his/her own set of case variables and personal values.
  - Weighing medical, surgical, financial, psychosocial, ethical considerations
  - Developing a consensus of a multidisciplinary team
  - Projecting who might make optimal transplantation candidates at the optimal time

“Difficult” Patients

- Common Themes
  - HCPs feel a lack of control
  - Patient appears to dictate the content of consultation
  - Feeling a stalemate
  - Patient seems to ignore advice and may even obstruct attempts to bring about improvement

Patient Selection Process

- Summary/Best Practices:
  - The process should be transparent and consistent.
  - Patients should know the program’s policies regarding the patient selection process, including:
    - Exclusion criteria (medical & psychosocial)
    - Behavior contracts
    - Review process/team meeting
    - Right to second opinion at your facility or elsewhere
    - Option to seek listing at other facilities

“Difficult” Patients

- Types of “Difficult” Patients
  - Manipulative Patients: Play on the guilt of others; threatening rage, legal action, or suicide.

  - Somatizing Patients: Present with exaggerated symptoms; comorbid anxiety, depression, personality disorders. (Doctor shoppers)

  - Frequent Fliers: Number of visits; stems from misinformation, loneliness, or “worried well”

Psychosocial Considerations

- Can we consider psychosocial outcomes? Yes!
- There is scientific evidence that matters such as mental health hx, social supports, compliance, and substance use can impact transplant outcomes.

“Difficult” Patients

- Impact They Create
  - Emotionally draining
  - Overtax staffing resources
  - They can “split” team members
  - Their negative behavior can adversely affect the success of their transplant (e.g., noncompliance)
“Difficult” Patients

• What Can You Do About It?
  – Don’t get drawn into the conflict
  – Be aware of your own emotions
  – Attempt to understand their expectations
  – Avoid cycle of diagnostic testing and referrals
  – Regard the patient as a new patient; conduct information gathering again
  – Use behavior contracts
  – Educate them on importance of therapeutic alliance

Enhancing Communication with Patients and Families

• Get beyond the surface:
  – “What makes you most uncomfortable about ...?”
  – “What would you need to know in order to accept...?”
• Well-constructed questions increasing understanding and establish relationships.
• Don’t assume you understand intentions and motivations (e.g., brain death cases)

“Difficult” Patients

• It’s OK to end relationship (de-list) but ...
  – Give them plenty of warnings
  – You should refer them to another TC
  – Provide contact information; facilitate referral
  – Give them time to make transition

Enhancing Communication with Patients and Families

• Develop ways of asking questions that do not curtail conversation:
  – “Do you understand?” is a pass/fail question
  – Better: “Is there anything you’d like more information about?”
• Explore areas of misunderstanding
  – “Is there anything I’ve said that does not make sense to you?”
ABTC Vision

- A certified transplant professional will provide continuum quality care to all organ donors, transplant candidates, transplant recipients and their families.

American Board for Transplant Certification

- Independent, not for profit organization founded in 1988.
- First examinations for Certified Clinical Transplant Coordinators (CCTC) and Certified Clinical Procurement Coordinators (CPTC) given in 1988.
- Currently offering four examinations.

American Board for Transplant Certification

- Certification for Clinical Coordinators (CCTC)
- Certification for Clinical Procurement Coordinators (CPTC)
- Certification for Clinical Transplant Nurses (CCTN)
- Certification for Transplant Preservationist (CTP)

ABTC Mission

- The American Board for Transplant Certification establishes standards of competence through certification and recertification of transplant professionals to advance the profession and protect the public.

American Board for Transplant Certification

- Current members:
  - CCTC 1191
  - CPTC 659
  - CCTN 364
  - CTP 57
Organization Structure

- Board of Governors
  - President, Vice-President, Secretary and Treasurer
  - Committee Chairs
  - At Large Members from each certification (elected by membership)

How Exam Content is Derived

- ABTC contracts with the testing agency Applied Measurement Professionals for examination development
- Under the instruction of a measurement professional, ABTC forms a committee of content experts to develop a job task analysis and gather published content materials

Committees

- Clinical Coordinator Examination
- Procurement Coordinator Examination
- Transplant Nurse Examination

- Continuing Certification
- Judiciary
- Marketing
- Finance

How Exam Content is Derived

- Job Task Analysis Survey is distributed to practicing professionals. Ideally to both certified and non-certified practitioners
- Survey data is compiled and a committee of content expert reviews the information
- Committee makes decisions based on decision consistency rules set in advance on what tasks meet these requirements

Purpose of Certification

- Establishes a standard level of competency for professionals within the same industry
- Maintains the public consumer’s trust in the industry
- Provides industry partners with benchmarks for potential sources of risk and improvement

How Exam Content is Derived

- Any tasks not given a critical/significant rating are “tossed out”
- After committee has rated all critical tasks cognitive levels are assigned to each task – recall, application or analysis
- Committee again under instruction from measurement professional determines the distribution of cognitive level tasks over the entire exam content domain
CCTC/CPTC/CCTN/CTP Examinations
- 175 multiple choice questions
  - 25 of the 175 questions are "pre-test"
- Online computer based testing
- Choice of over 150 testing sites nationwide
- Candidate picks the date & time (M-F, certain holidays excluded)
- Score generated before candidate leaves testing site

CPTC Major Content Areas
- Plan, Conduct and Evaluate Public and Professional Education
- Evaluate and Manage a Potential Donor
- Facilitate Organ Allocation, Recovery & Preservation

Exam Specifications
How to Use this Tool

CCTN Major Content Areas
- Pre-transplantation Care
- Post-Transplantation Monitoring & Maintenance
- Pharmacological Therapeutics
- Education and Discharge
- Professional Responsibilities

CCTC Major Content Areas
- Evaluation & Preparation for Transplant
- Post Transplant Care

CTP Major Content Areas
- Professional Practice
- Organ Recovery
- Aseptic Technique
- Organ Preservation
- Specimen Collection
- Packaging, Labeling & Shipping
Candidate Handbook

- Contains detailed examination content, references, sample questions and detailed information on examination application and administration process
- Download from www.ABTC.net or call 913-895-4603

Self Assessment Examination (SAE)

- CCTN
- CCTC
- CPTC
- 50-75 test questions
- Cost: $60.00
- Web based product available for purchase from the ABTC website

Examination Application Process

- Must be employed for 12 months
- Download application and handbook, register and pay at www.ABTC.net OR
- Call ABTC to Request Handbook packet at 913-599-0198
- Cost: $425.00

Recertification Policies

- Must recertify every three years
- May re-examine OR
- By providing continuing education evidence
  - 60 contact hours for single certification
  - 90 contact hours for dual certification
  - 90 contact hours for triple certification
- Cost: $300.00

Examination Administration Process

- Exam candidates have 90 days to schedule an examination appointment after receiving notification from ABTC that your application has been accepted
- Online applicants may schedule their testing appointment in the same session as applying to take the exam

Examination Item Writing

- Draft items submitted to ABTC Office
- Format outlined @ www.ABTC.net
- Referenced to Literature & Content Outline
- Refined by Exam Committee
- 3-5 Category 1 Continuing Education Points for Transplant Certification (CEPTCs)/Item
Approved Providers

- $1500 annually for unlimited programs and CEPTCs
- Less than what you would spend sending 1 staff member to a national conference
- Simplified the application and renewal process
- Allows your organization to provide Cat 1 CEPTCs for in-house education

More how to support certification

- Work with your Magnet Champion – average specialty certification rate is 50% in Magnet facilities
- Offer CEPTC’s for Chapter meetings and Symposums

What’s new

What’s Next?
Investigating new opportunities
- Family Requester – investigating
- Financial Coordinators – investigating
Aging for Examination Accreditation
Through National Commission on Certifying Agencies (NCQA) deadline for application is August 30, 2010
CPTN examination fees decreased to $325
starting 1/1/2011

Thank you

Questions?

How you can support certification

How You Can Support Certification
- Joint Commission regulations require CCTC certification – be sure you meet req
- Most employers require certification and provide reimbursement or incentives
- Request your OPD or Transplant Program to become an Approved Provider
- Ensure your employability by maintaining your certification – no matter where you work by recertifying
Infectious Disease Assessment in the Organ Donor

Disclosures

- Research Support*
  - Roche (oseltamivir)
  - Biocryst (peramivir)
  - ViroPharma (maribavir)
  - ADMA (RSV Ig)
  - Chimerix (CMX-001)
  - ViraCor
- Consultation
  - ViraCor, Abbott Molecular, Biogen Idec
- DSMB: Chimerix

As of September 18, 2010. *Paid to Northwestern University.

Infection in Transplantation

- 25% of cadaver kidneys have bacterial contamination
- Occurs in >2/3 of patients in the first year
- Remains a leading cause of death
- Risks
  - Epidemiological exposure and history
  - Net state of immunosuppression
  - Time after transplant
  - Efficacy of prophylaxis

Donor-Derived Infections

- Definition: Any infection of a recipient that results from an infection present in the donor and transmitted by the donated organ
- Incidence: unknown (~0.2%)
- Types:
  - Expected: EBV, CMV, Toxo
  - Unexpected
    - LCMV, Rabies, malaria
    - Bacterial, TB, fungal pathogens
Unique Issues in Organ Donor Screening

- Restricted timeline
- Different Screening Paradigm
  - No expectation for “Zero Risk”
- Donor history
- Serology-based Screening
- Variable NAT capacity and practice
- No standard policy with regard to hemodilution
- Incomplete Data Collection

Case 1

- Continued with fever, LFTs increased
- Seizure (Hypoxemic)
- Progressive “sepsis” with elevated LFTs and renal dysfunction
- Call from another Transplant ID doctor: “how is your recipient doing?”

Case 1

- Donor
  - Previously healthy woman who was brain dead secondary to a hemorrhagic stroke
  - Donated liver, lungs, kidneys, corneas, skin
  - Purchased a hamster for her son a few weeks prior to death

Significant Organ Shortage

![Graph showing significant organ shortage over years.

- Patients Waiting at Year End
- Deceased Donor Transplants
- Deceased Donors
- Recovered
- Waiting List Deaths*

2009 DATA

- Donor Transplants: 14,484
- Waitlisted Candidates: 105,987
- Deaths on Waitlist: 9,848

*Waiting list death includes removals for death, too sick to transplant, and those from transplantation removals due to longest period seven days of removal from linkage to DSRP data. Based on OPTN data as of April 16, 2010.

Case 1

- 54 yo WM with HBV/HCV/HCC
- Day 5: Fever to 102.4, mild frontal HA since time of transplant
- IS: ATG, Tacrolimus, Azathioprine
- Abx: Pip-Tazo, HBig, 3TC, Famciclovir, TMP-SMX
- SH: Suburbs, Iron worker
- PE: Non-focal except for a tender RUE peripheral IV catheter

The Culprit

- A hamster is shown as a potential culprit.
Case 2

• Patient is a 56 yo WM
• Underwent OHT November 2005
  – Toxo D+/R–, CMV D+/R–
  – Pyramethamine-Sulfadiazine
  – Valganciclovir
• 9 days post-transplant
  – Donor has + blood cultures drawn the day prior to donation
  – Positive for Pseudomonas aeruginosa

Case 3

• One recipient was identified with post-transplant HCV & HIV infection with no obvious risk factors and negative pre-transplant testing
• Reported to OPO, UNOS, and CDC
• Donor
  – Negative serology for HIV & HCV
  – Appropriately labeled as “high risk” by PHS guidelines
  – Subsequent testing of post-transfusion serum was + for HIV and HCV by PCR
• All other recipients tested positive for HIV and HCV

Donor-Derived Infections: 2005-2009

<table>
<thead>
<tr>
<th>Source</th>
<th>Affected Organs</th>
<th># of Recipients</th>
<th># of Donors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Virus 1</td>
<td>Lungs</td>
<td>9</td>
<td>8</td>
</tr>
<tr>
<td>Bacteria</td>
<td></td>
<td>26</td>
<td>5</td>
</tr>
<tr>
<td>Fungus</td>
<td></td>
<td>10</td>
<td>8</td>
</tr>
<tr>
<td>Mycobacteria</td>
<td></td>
<td>26</td>
<td>10</td>
</tr>
<tr>
<td>Parasite</td>
<td></td>
<td>21</td>
<td>13</td>
</tr>
</tbody>
</table>

Donor-Derived Diseases: Regulations

• OPTN Policy 4.1 (Screening for HIV, High Risk Consenting)
• OPTN Policy 4.6 (Screening)
  – Addresses the screening of potential organ donors for transmissible diseases, conditions and malignancies
  – Any known transmissible conditions from the donor must be communicated to the transplant center (special consent)
• OPTN Policy 4.7 (Communication and DDD)
  – Directly addresses communications between centers, OPO’s and the Patient Safety Reporting Specialist
  – Transplant centers must notify the OPO within 24 hours of a known or suspected event
  – OPO is responsible for notifying the OPTN as soon as possible and transplant centers/tissue banks as soon as feasible: OPO initial report within 2 working days and final report at 45 days.
Which Are OPTN-Defined High Risk Donors?

- 32 year old homosexual male in a monogamous relationship
- 57 year old who used IV drugs in the 1960's (but not since)
- 21 year old with a new tattoo
- 23 year old prostitute
- 21 year old sexually promiscuous college sports player
- 3 year old born to an HIV infected mother

OPTN-Defined High Risk Donor Status Assessment?

- Tested for HIV? Why?
- Males: had sex with a male or sex with female as below?
- Females: had sex with a male who had sex with a male?
- Sex with someone with HIV, HBV, HCV, CMV, HSV
- Sex for drugs or money?
- Clotting factors or blood transfusions
- Exposure to HIV or HBV, HCV eg needle stick?
- Incarcerated? In the past year? >3 days?

PHS Donor Screening Recommendations

- Frank discussion, in simple language, with person giving consent about risk factors for transmission of HIV and then ascertainment of these potential risk factors.
- For all prospective donors, a blood sample obtained before any transfusions were administered (during the current hospital admission for inpatients) should be collected as close to the time of retrieval of tissue as possible. Samples should be tested for antibodies to both HIV-1 and HIV-2 by using FDA-licensed tests.
PHS Donor Exclusion Criteria

Behavior/History Exclusionary Criteria
1. Men who have had sex with another man in the preceding 5 years.
2. Persons who report nonmedical intravenous, intramuscular, or subcutaneous injections of drugs in the preceding 5 years.
3. Persons with hemophilia or related clotting disorders who have received human-derived clotting factor concentrates.
4. Men and women who have engaged in sex in exchange for money or drugs in the preceding 5 years.
5. Persons who have had sex in the preceding 12 months with any person described above or with suspected HIV.
6. Persons who have been exposed in the preceding 12 months to known or suspected HIV-infected blood.
7. Inmates of correctional systems.

Specific Exclusionary Criteria for Pediatric Donors
1. Children meeting any of the exclusionary criteria listed above for adults.
2. Children born to mothers with HIV infection or mothers who meet the behavioral or laboratory exclusionary criteria for adult donors should not be accepted as donors unless HIV infection can be definitely excluded.
3. Children <18 months of age who are born to mothers with or at risk for HIV infection or who have been breast fed within the past 12 months should not be accepted as donors regardless of their HIV test results.

PHS Guidelines: Summary

- Donor Screening
  - History and examination
  - Laboratory testing
  - Exclusion criteria
  - Safe specimens

- Post-Transplant Management
  - Consent of the recipient (OPTN Policy)
  - Post-transplant testing
  - Post-transplant reporting

Risk of Transmission by Risk Group

<table>
<thead>
<tr>
<th>Risk per 10,000 donors</th>
<th>HIV ELISA</th>
<th>HIV NAT</th>
<th>HCV ELISA</th>
<th>HCV NAT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Window Period</td>
<td>22 days</td>
<td>9 days</td>
<td>66 days</td>
<td>7 days</td>
</tr>
<tr>
<td>Men who have sex with men</td>
<td>8.3</td>
<td>3.4</td>
<td>36.0</td>
<td>3.8</td>
</tr>
<tr>
<td>IV Drug Users</td>
<td>12.9</td>
<td>5.3</td>
<td>350.0</td>
<td>37.8</td>
</tr>
<tr>
<td>Hemophiliacs</td>
<td>0.05</td>
<td>0.02</td>
<td>0.46</td>
<td>0.05</td>
</tr>
<tr>
<td>Prostitutes</td>
<td>2.9</td>
<td>1.2</td>
<td>107.8</td>
<td>11.5</td>
</tr>
<tr>
<td>Partner with the above</td>
<td>2.7</td>
<td>1.1</td>
<td>126.2</td>
<td>13.5</td>
</tr>
<tr>
<td>Blood product exposure</td>
<td>1.3</td>
<td>0.5</td>
<td>22.0</td>
<td>2.3</td>
</tr>
<tr>
<td>Incarceration</td>
<td>1.5</td>
<td>0.6</td>
<td>68.6</td>
<td>7.3</td>
</tr>
</tbody>
</table>

Which Donors are OPTN-Defined High Risk Donors?

- OPTN-Defined High Risk Donors
  - 32 year old homosexual male in a monogamous relationship
  - 23 year old prostitute
- Not OPTN-Defined High Risk Donors
  - 57 year old who used IV drugs in the 1960’s
  - 21 year old with a new tattoo
  - 21 year old sexually promiscuous college sports player
- Need more information
  - 3 year old born to an HIV infected mother

PHS Guidelines: Recipient Care

- Only use organs from increased-risk donors if "the risk to the recipient of not performing the transplant is deemed to be greater than the risk of HIV transmission and disease."
- Health-care providers for transplant recipients and the recipients themselves should be aware of the small but potential risk of infections, including HIV, from transplanted organs and tissues. The recipient’s informed consent to the transplant should include acknowledgment of the risks, including transmission of HIV and other infections.
- Recipients should be screened post-transplant to assess for disease transmission.
Critical Balance

- Organ Availability
- Patient Safety

Social History

- Married, divorced, sexual practice, tested for HIV?
- Living situation/Incarceration
- Smoking history
- Drug history (IV, recreational, OTC)
- Tatoo history (where, when, who)
- Transfusion history
- Travel history (military?)
- Work history (occupational exposures)
- Pets

History and Physical

- General
  - General health—well until
  - Age—appears stated age
  - Weight loss—cancer, TB, thyroid dz, depression
- PMH/PSH
- Allergies/Medications
- SH/FH/ROS
- PE (look, listen, feel)

HIV and Hepatitis Risks

- Tested for HIV? Why?
- Males: had sex with a male or sex with female as below?
- Females: had sex with a male who had sex with a male?
- Sex with someone with HIV, HBV, HCV, CMV, HSV
- Sex for drugs or money?
- Clotting factors or blood transfusions
- Exposure to HIV or HBV, HCV eg needle stick?
- Incarcerated? In the past year? >3 days?

Past Medical History

- PMH
  - Hospital admissions
  - Physician visits
- PSH
- Childhood illnesses
- Vaccinations
- Allergies
- Medications (past and current)

Review of Systems

- Constitutional: Fatigue, malaise, fever, chills, sweats, rigors, weight change
- Skin: rash, jaundice, pruritus, moles, exczema
- HEENT: Head ache, photophobia, otalgia, sore throat, neck stiffness
- Cor/Pul: Cough, SOB, chest pain, swelling
- GI: Nausea, vomiting, diarrhea,
- GU: Frequency, dysuria, nocturia, incontinence, UTI's, BPH, stones
- MSK: fractures, arthritis, bone disease
- Endo: diabetes, thyroid disease
- Neuro/Psych: tremors, mental status changes
- ID: TB, PPD
Symptoms and Signs of Infection

- **Symptoms**
  - Constitutional: Fatigue, malaise, fever, chills, sweats, rigors, weight change
  - Skin: rash, jaundice, nail changes
  - HEENT: Head ache, photophobia, otalgia, sore throat, neck stiffness
  - Cor/Pul: Cough, SOB, chest pain, swelling
  - GI: Nausea, vomiting, diarrhea,
  - GU: Frequency, dysuria, nocturia, incontinence, H/O BPH, stones
  - Neuro/Psych: tremors,
- **Signs**
  - CBC: low WBC=viral, high WBC=bacterial, anemia=viral, thrombocytopenia=viral
  - BMP: low sodium (think Erlichia, mycoplasma)
  - LFT’s: viral hepatitis, Erlichia

**Physical Exam**

- **Vital Signs:**
  - Temp, HR, RR, WT, I/O’s, SaO₂
  - Hemodynamics (CVP, PCW, CO, SVR) Ventilator settings (FIO2, RR, PEEP, ABG)
- **General/Skin:**
  - Clean, well kempt vs dirty, disheveled
  - Scars, tattoos, piercings,
  - Wounds, bruising, jaundice, rash, moles
  - Lines, tubes, and drains

**Physical Exam (cont)**

- **HEENT:**
  - Jaundiced,
  - blood in ears, nose,
  - condition of dentition,
  - adenopathy
- **Cor:**
  - Tachy
  - Murmurs (endocarditis),
  - Rubs (infectious vs traumatic pericarditis)

**Physical Exam (cont)**

- **Pulmonary:**
  - Response to ventilator
  - Duration of intubation
  - Quality of breath sounds
  - Chest tube
- **Abdomen:**
  - Distention, masses, bowel sounds
  - Rectal

**Physical Exam (cont)**

- **GU**
  - Rectal exam
  - Vaginal exam
- **Brain Dead**
  1. Cerebral unresponsiveness (Coma)
  2. No spontaneous motor activity
  3. Positive apnea test
  4. Absence of cranial reflexes
  5. Unresponsive to upper & lower airway stimuli

**Laboratory Evaluation**

- **CBC**
  - Low WBC: medications, malignancy
  - Low WBC/high Monos or lymphs: viral
  - High WBC/MMN’s: bacterial; stress, steroids
  - High Eosinophils: parasite, fungus, meds
  - Anemia: viral, malignancy, malnutrition
  - Low platelets: DIC, sequestration
- **Cultures**
  - Urinalysis and culture
  - Blood culture and sensitivity
  - Stools for Ova and Parasite
  - Culture of any affected body fluid
- **Radiologic data**
  - CXR, US and CT as needed: Pneumonia, ARDS
Screening for Infections

- Antigen detection
- Serology
  - Tests for antibody response to infection
  - ELISA: most common techniques
    - Enzyme-Linked ImmunoSorbent Assay (ELISA)
    - Enzyme ImmunoAssay (EIA) = ELISA
  - Can be qualitative or quantitative
- Molecular/Nucleic Acid Testing
  - Polymerase chain reaction (PCR)

Serology: Limitations

- Can have false negative results
  - Window Period
  - Dilution of antibodies
    - Blood products
    - IV fluid
- Not everyone develops and maintains antibody response of same magnitude

ELISA: Indirect & Sandwich

http://mservet.arslons.edu/Leaderboard/ELISAvia/ELISA.png
http://mservet.arslons.edu/Leaderboard/ELISAvia/ELISA_Gross.jpg

Serologic Screening for Organ Donors

- Hepatitis A: HAAb
- Hepatitis B: HBsAg (surface), HbcAb (core)
- Hepatitis C: HCAb ELISA (second-generation)
- HIV (Human Immunodeficiency Virus): ELISA
- Syphilis: VDRL or RPR
- CMV
- Toxoplasmosis (For Heart or Composite Donors)
- ?West Nile Virus, ?Rabies, ?C-Jacob

Screening for Infectious Diseases

- Screening limitations
  - Viremia
  - Nucleic acid testing
  - Serologic testing
  - Serologic conversion

<table>
<thead>
<tr>
<th>WINDOW</th>
<th>Virus</th>
<th>Serologic conversion</th>
<th>Serologic testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure</td>
<td>HBV</td>
<td>60 days</td>
<td>20 days</td>
</tr>
<tr>
<td></td>
<td>HCV</td>
<td>70 days</td>
<td>7 days</td>
</tr>
<tr>
<td></td>
<td>HIV</td>
<td>23 days</td>
<td>7 days</td>
</tr>
</tbody>
</table>

CYTOMEGALOVIRUS (CMV)

- Largest human herpesvirus
- Ubiquitous in the population
  - 1% congenital infection
  - 5-10% perinatal infection
  - 40-90% of adults seropositive
- Usually asymptomatic in normal hosts
Cytomegalovirus (CMV)

- Disease occurs through reactivation of latent disease or new infection

<table>
<thead>
<tr>
<th>Risk Group</th>
<th>Viremia</th>
<th>Disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>D+/R-</td>
<td>80-100%</td>
<td>40-60%</td>
</tr>
<tr>
<td>D+/R+</td>
<td>30-60%</td>
<td>20-40%</td>
</tr>
<tr>
<td>D-/R-</td>
<td>2-4%</td>
<td>ND</td>
</tr>
</tbody>
</table>

- Prevention:
  - Universal prophylaxis
  - Pre-emptive therapy/universal monitoring

Hepatitis B

- All donors should be tested for Hepatitis B Surface Antigen (HBsAg)

- Hepatitis B surface antigen (HBsAg) positive donors:
  - Are typically only used in SOT recipients that are seropositive as well
  - But can be used, rarely, for seronegative recipients but it requires the post-transplant use of anti-HBV medication and/or anti-HBV antibody therapies

Hepatitis in Transplantation

- Hepatitis A (DNA virus)
  - Rare cause of fulminant failure
  - Gamma Globulin 0.02 ml/kg x1
  - Vaccinate pre-transplant

- Hepatitis B (DNA virus)
  - Vaccinate pre-transplant
  - High morbidity and mortality with active disease
    - HBIG, Lamivudine (3TC), Adefovir

- Hepatitis C (RNA virus)
  - Most common cause of ESLD
  - 100% recurrence rate

Hepatitis B

- Because anti-HB core antibody (HbcAb) might be the only marker of early HBV infection (or of a continuous DNA circulation), and because anti-Hbc+ donors can transmit HBV, anti-HbcAb should be routinely tested in all organ donors

- Anti-HbcAb determination is not influenced by exposure to hepatitis B vaccine

- Some experts also recommend routine testing of anti-HbsAb because of a reduced risk of transmission by extrahepatic organs by HbsAb+ donors
Hepatitis B

- Isolated anti-HBs+, HBsAg- and anti-HBcAb-negative are not uncommon in four situations:
  - Hep B vaccination
  - Hep B immunoglobulin administration
  - Blood product transfusion from an immunized donor
  - Previous Hep B infection
- Hepatitis B vaccination results
  - HBs Ab+, but not HBcAb +

Hepatitis C (HCV)

- About 5% of all organ donors are positive for antibody to HCV (anti-HCV)
- The presence of anti-HCV does not protect against donor organ contamination
- HCV is transmitted by 50-100% of organs from anti-HCV+ donors to anti-HCV- recipients
- 50% of anti-HCV+ patients have detectable hepatitis C viremia by PCR

Human T Cell Lymphotropic Virus Type 1 and 2

- HTLV-1 is endemic in Japan, Australia and Caribbean
- HTLV-2 has not been associated with any disease so far
- Most infections are asymptomatic
- Seroprevalence in Europe and US in blood donors is < 0.5%
- Transmission through solid-organ transplantation has not been reported in the United States
  - transmission have been documented in Japan and Spain

Toxoplasmosis

- Heart and Composite Tissue recipients are at highest risk because the organism encysts in myocytes
- The highest risk situation is when Toxoplasma species-seronegative recipient receives a heart from a Toxoplasma species-seropositive donor
- Serological screening of the recipient can identify seronegative individuals at potential risk who should receive prophylaxis after transplantation with TMP-SMX, atovaquone or pyrimethamine
- Without prophylaxis, 50% of seronegative heart acquire Toxo through the organ of a seropositive donor

Cadaveric Donor Infection Prophylaxis

- Cefazolin
- Vancomycin if penicillin/cephalosporin allergy
Conclusions

- Transmission of infectious disease with organ donation is common
- Proper assessment and evaluation allows for appropriate prophylaxis or preemptive management of the infection or prevention of the transplant
- Newer techniques are making evaluation more rapid and comprehensive

Questions?
Medical Management of the Pediatric Organ Donor

*Thomas A. Nakagawa, M.D, FAAP, FCCM*

Professor, Anesthesiology and Pediatrics
Department of Anesthesiology and Pediatrics
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Director, Pediatric Critical Care
Brenner Children's Hospital at
Wake Forest University Baptist Medical Center
Winston-Salem, NC

Questions to Run On

- What are anatomical and physiologic differences between children and adults that factor into pediatric donor management?
- What are some unique issues related to pediatric donation?
- How are management and pharmacologic treatment to maintain physiologic parameters in the potential pediatric organ donor different from the adult donor?

The Facts about Pediatric Donation

- 1,767 children are waiting for a needed organ*
- Children make up 2% of the total national waitlist
- Approximately 175 children die annually waiting for a needed organ and another 30-40 children are removed from the national waiting list because their condition deteriorates making them ineligible for organ transplantation
- Children less than 1 year of age have the highest death rate waiting for an organ

*OPTN data. Accessed October 13, 2009  www.OPTN.org*
The Decline in Pediatric Donors

• Missed opportunities for donation
  – Families of potential pediatric donors may not be given the opportunity to donate
• Families are declining the option of organ donation
• Opportunities for donation may be denied in cases where abusive trauma has claimed the life of a child

Declining Mortality Rates in Children

• Improved technologies available in critical care medicine
• Improved surgical techniques
• Eradication of life-threatening diseases
• Safety restraints
• Safety education and awareness
• Involvement of critical care specialists

Anatomic and Physiologic Differences in Children

• Respiratory system
  – Airway
    • Increased airway resistance due to small airways
    • Chest wall is more compliant
    • Respiratory muscles are less well developed
• Cardiovascular
  – Higher resting heart rate to maintain CO
  – Generate smaller stroke volumes
  – Drastic decreases in heart rate result in decreased CO

Normal Heart Rate a Blood Pressure Parameters for Children

<table>
<thead>
<tr>
<th>Heart rates</th>
<th>Blood pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Systolic</td>
</tr>
<tr>
<td>Neonate</td>
<td>90-180</td>
</tr>
<tr>
<td>Infants (9 months)</td>
<td>80-160</td>
</tr>
<tr>
<td>Toddler (2 years)</td>
<td>60-110</td>
</tr>
<tr>
<td>School age (7 years)</td>
<td>60-110</td>
</tr>
<tr>
<td>Adolescent (15 years)</td>
<td>50-90</td>
</tr>
</tbody>
</table>

Minimum systolic blood pressure 70 + 2 x (age in years)

Anatomic and Physiologic Differences in Children

• Larger body surface area
  – Rapid heat loss and temperature instability
• Limited glycogen stores
  – Hypoglycemia
• Limited catecholamine stores
• Neurologically different than adults
  – Brain has a higher water content
  – Larger subarachnoid space
• Psychologically different from adults

Special Circumstances Regarding Pediatric Organ Donors

• Limited number of pediatric organ donors
  – Relatively healthy population
  – Most children die from cardiac or respiratory causes although brain death does occur in children
• Many children that die suddenly as a result of traumatic or non-traumatic brain injury will have isolated injuries making them almost ideal candidates from the perspective of the transplant team
• Children do not typically have drivers licenses or living wills stating their wishes regarding organ donation
Special Circumstances (cont)

- Pediatric intensive care units provide care for children with all types of injury and illness
- Pediatric intensivists are actively involved with patient care
- Pediatric intensivists are usually the first to have in-depth interactions with family members
- Conversations with the family are coordinated by pediatric intensivists which helps to reduce confusion related to patient care issues

Special Considerations for Drug Dosing in Children

- Limited vascular access
- Smaller catheters limit fluid administration
- Administration of continuous infusions may require concentration of medications to avoid administering excessive fluids to small children
- Drug compatibility issues

Special Considerations for Drug Dosing in Children

- Many pharmacologic agents are based upon body weight of the child.
  - Consider the ideal body weight of the child
- Certain medications may induce metabolism of other medications
  - Medications that increase Cytochrome P450 activity
    - Anticonvulsants
      - Phenytoin
- Metabolic rate and drug metabolism are different in children
- Pharmacokinetic activity can be affected by organ system dysfunction
  - Renal insufficiency/failure
  - Hepatic insufficiency/failure

Special Considerations Regarding Clinical Management of Pediatric Organ Donors

- Equipment issues
  - Airway
  - Vascular access and fluid issues
- Size limitations may restrict transplantation of organs
- Technically challenging procedures in smaller children
- Emotional aspects following the death of the child
- Trained staff who understand unique issues related to caring for children and their families

Route of Administration

- Onset and duration of action
- Consideration of drug effects should be entertained as one selects a route of drug administration
  - Oral
  - Intravenous
  - Intramuscular
  - Intranasal
  - Rectal
  - Transdermal / Topical
  - Inhalation

Brain Death in Children

- Certain medications may induce metabolism of other medications
- Metabolic rate and drug metabolism are different in children
- Pharmacokinetic activity can be affected by organ system dysfunction
  - Renal insufficiency/failure
  - Hepatic insufficiency/failure
Diagnosing Brain Death in Children

- Based upon the absence of brainstem and hemispheric function
- Patients in a persistent vegetative state are not brain dead
- It is not necessary to diagnose brain death in order to discontinue extraordinary measures of support or to tell the parents the child's outlook is hopeless
- Once brain death criteria are met, the patient is legally dead

Important Considerations When Diagnosing Brain Death

- Observation/waiting times have never been validated
- No recommendations were for newborns < 7 days of age because of limited data in this age group
  - Misinterpretation of recommendations
  - They do not imply that testing should not be done
  - They do not imply that testing is unreliable
  - They do not state that brain death cannot be declared in infants under 7 days of age

Ancillary Tests That May Aid in the Diagnosis of Brain Death

- EEG
- Cerebral angiography
- Radionuclide Scans
- Intracranial pressure monitoring
- Brainstem evoked responses
- Doppler sonography

Guidelines for the determination of brain death in children:
1. Coma and apnea must occur concurrently. The patient must exhibit complete loss of consciousness, ventilation, and cardiovascular function.
2. Absence of brainstem function as defined by:
   a. Unresponsiveness to painful stimuli
   b. Absence of oculocephalic and oculovestibular reflexes
   c. Absence of corneal, abdominal, and withdrawal reflexes
   d. Absence of pupillary responses to light
   e. Absence of motor responses to pain
   f. Absence of cerebral circulatory responses to blood pressure
3. Observation/waiting times have never been validated.
4. Observation/waiting times have never been validated.
5. Observation/waiting times have never been validated.
6. Observation/waiting times have never been validated.
Ancillary Tests May Aid in the Diagnosis of Brain Death

- Ancillary tests can provide additional information to help confirm brain death in situations where clinical examination and apnea testing are not feasible or cannot be completed because of undue circumstance
  - Facial injury
  - Acute lung injury
  - Cardiovascular instability
  - Presence of myoclonic or unusual muscle movement
  - Abnormal muscle contractions
  - Presence of high levels of sedating drugs or neuromuscular blocking agents
  - Barbiturate coma
- Ancillary tests are not mandatory
- Ancillary tests may provide another layer of comfort to the physician who is uncomfortable declaring brain death on clinical exam alone
- Ancillary tests may reduce observation periods thus increasing potential for retrieving viable transplant tissue
- Ancillary tests may also delay or prolong observation periods

Understanding Limitations of Pediatric Brain Death Guidelines

- Guidelines are 20 years old
- Guidelines did not specifically address the trauma population
- Guidelines were based upon limited clinical experience at the time of publication
- Guidelines were based upon age criteria
- No guidelines for neurologic death in neonates
- Waiting times have never been validated

Considerations When Diagnosing Brain Death in Children

- One must determine the cause of coma and brain injury
- Correction of toxic and metabolic disturbances, hypotension, hypovolemia and hypothermia must occur
- Determination of brain death, duration of observation, and need for confirmatory tests should be based on history and clinical examination

Pitfalls in Diagnosing Brain Death in Children

- Anticholinergic drugs
- Neuromuscular blocking agents
- High levels of sedative hypnotic or anesthetic agents
- Hemodynamic instability
- Hypothermia

Considerations When Diagnosing Brain Death in Children

- Many times the cause of the child’s neurologic demise is known
- Based upon presentation and examination many times we know that there will be no hope for survival
- The waiting period may be extended or decreased depending upon medical, social and family related issues

Additional Considerations

- Regional variances for determination of brain death occur
- Guidelines for the determination of brain death will vary from state to state and institution to institution
- Become familiar with the guidelines and the physicians caring for patients in your area
Management of the Pediatric Organ Donor

• Requires a team approach
  – Physicians
  – Nurses
  – Respiratory therapists
  – Social workers
  – Chaplains
  – Translators
  – Child life specialists
  – Transplant professionals

Key Points

• Prevention and/or correction of
  – Hypoxia
  – Hypo or hypercarbia
  – Hypo or hypertension
  – Hypo or hyperthermia
  – Hypo or hyperglycemia

Management of the Pediatric Organ Donor

• The management of the pediatric organ donor will be dictated by regional standards of care and the physicians caring for the child
• Children are best cared for in a pediatric center with trained staff who are familiar with the unique needs of children and families
• Consultation and collaboration with a pediatric intensive care specialist is paramount to ensure the best possible outcome for organ recovery

Management Goals

• Resuscitation
• Oxygen delivery to the tissues
• Hydration and perfusion
• Restoration of normal ventilation
• Thermal regulation
• Regulation of neuroendocrine function
• Continued support for the family

The Dying Brain

• As brain death occurs multiple physiologic changes occur in the body
  – Metabolic changes
    • Brain consumes 15-20% of cardiac output
    • Decreased CO\textsubscript{2} production
    • Decreased glucose utilization
    • Thermoregulatory instability
  – Neuroendocrine dysfunction
    • Fluid and electrolyte disturbances
    • Cardiovascular instability
Impairment of the HPA axis

- Impaired anterior pituitary function results in loss of TSH and ACTH production
- Impaired posterior pituitary function results in loss of anti-diuretic hormone

Oxygenation and Ventilation

- Impaired oxygenation and ventilation occurs secondary to:
  - Underlying lung disease
    - Trauma
    - Pulmonary hemorrhage or contusion
    - Inhalation injury/thermal injury
    - Barotrauma
  - Infection
    - Pneumonia
  - Impaired cardiac output
  - Anemia
  - Inadequate ventilatory support

Additional Considerations

- Effects of neurologic injury and death
  - Significant inflammatory reaction that results in cytokinemia secondary to impending or completion of neurologic death
  - Patients may require dopamine for hemodynamic support
  - Inhibition or complete loss of TSH release from the pituitary as neurologic death occurs

- Potential donor
  - Relative hypothyroid state from the CNS insult and therapy to maintain hemodynamic stability
  - Upon completion of neurologic death becomes athyroid

Thermoregulatory Alterations

- Hypothermia
  - Hypothalamic dysfunction
  - Vasodilation secondary to loss of vascular tone resulting in heat loss

- Treatment
  - Warming lights, blankets/pads (Bear hugger)
  - Warm IV’s
  - Increase heater temperature on the ventilator humidifier
  - Environmental warming

Impaired Oxygenation and Ventilation (cont)

- Pulmonary edema
  - Cardiac failure
  - Fluid overload
  - Capillary leak secondary to trauma or infection
  - Atelectasis

Impaired Oxygenation

- Clinical scenario:
  - Child abruptly has decreased oxygen saturations

- Treatment
  - Examine the patient
  - Manual ventilation with 100% oxygen
  - CXR

- Determine the cause for acute hypoxemia
  - Kinked, displaced, or dislodged ETT
  - Mucous plugging
  - Lavage and suction
  - Bronchospasm
  - Treatment with bronchodilators
  - Pneumothorax
    - Secondary to high airway pressures
Oxygenation

Impact on the ETU

Improving Oxygenation

• Oxygenation is dependent upon
  – Cardiac output = HR x SV
  – Hemoglobin
  – Fraction of inspired oxygen (FI02)

• Strategy to improve oxygenation
  – Appropriate cardiac output
  – Transfusion of PRBC’s
  – Ventilator manipulation
  – Alter pulmonary vascular resistance (PVR)

Impaired Oxygenation

• Review non-invasive monitoring patterns
  – Pulse oximetry
  – Capnography
  – ETCO3 monitoring
• Blood gas analysis
• Ventilator parameters
  – Increased PIP or a decrease in tidal volume indicates a change in compliance
  – Compliance is determined by pressure and volume
  – Compliance = ΔV/ΔP

Treatment of Oxygenation Abnormalities

• Improving and maintaining oxygenation
  – Mechanical ventilation
    • Increase FI02
    – Use high concentrations of oxygen only as needed
    – High concentrations of oxygen are toxic to pneumocytes and interfere with surfactant production
    – High concentrations of oxygen promote atelectasis
    – The lowest concentration of inspired oxygen should be used
    + 40% FI02 is a safe concentration
  • Increase PEEP
    – Recruits alveoli
    – Maintains FRC
    – Treatment of pulmonary edema

Treatment of Oxygenation Abnormalities (cont)

• Increase inspiratory time (TI)
  – Remember this will decrease expiratory time. To avoid stacking breaths the I:E ratio should not exceed 1:1
  – Avoid excessive hyperventilation
  • Alters pulmonary vascular resistance (PVR)
  – Treat pulmonary edema
    • PEEP
    – Diuretic therapy
    – Prevent atelectasis
    – Aggressive pulmonary toilet
    – Prevention of barotrauma

Oxygenation and Ventilation Are Not One in the Same

• Oxygenation
  – CaO2
    • Hgb
    • FI02
  – Cardiac output
    • SV x HR
  – Impaired oxygen delivery to the tissues results in a metabolic acidosis

• Ventilation
  – Minute ventilation
    • RR x Vt
  – Alteration of ventilation results in respiratory acidosis or alkalosis

Appropriate Placement of the ETU

• CXR should be performed to check placement of the ETU
• Proper depth of the ETU
  – 3 x size of the ETU
  – 10 + age in years
  (1 year of age or greater)
**Treatment of Oxygenation Abnormalities (cont)**

- As aggressive volume replacement for hypovolemia occurs, exacerbation of pulmonary edema is likely
  - Increasing PEEP may help reduce pulmonary edema
  - Increased levels of PEEP may alter pre-load

**Treatment of Oxygenation Abnormalities (cont)**

- Improve cardiac output \( [\text{CO} = (\text{HR} \times \text{SV})] \)
  - Volume support for hypovolemia
  - Inotropic support
  - Transfusion of pRBC's
  - Increases CaO₂
- Control of PVR
  - Oxygen
  - Inodilators
  - Inhaled nitric oxide
  - Alkalization
    - Metabolic
    - Respiratory

**Ventilation Abnormalities**

- Loss of respiratory regulation
  - Alteration of pH
    - Respiratory alkalosis is common
    - Respiratory acidosis can occur from inadequate ventilation
  - Loss of skeletal muscle stimulation results in chest compliance changes
  - Decline in CO₂ production from the brain
  - Alteration of oxygen delivery to the tissues
    - Shift of hemoglobin/oxygen dissociation curve

**Treatment of Ventilation Abnormalities**

- Adjustment of minute ventilation \([\text{RR} \times \text{Vt}]\)
  - PIP or Vt should be adjusted for adequate chest rise
    - Excessive pressures increase the risk of barotrauma
  - Adjust respiratory rate normalize PaCO₂
    - Avoid hyperventilation
    - ETCO₂ monitoring may be beneficial and can limit blood gas analysis

**Clinical Teaching Point**

- Oxygen saturation does not equal oxygen delivery to the tissues
- Oxygen saturation tells you the percentage of hemoglobin that is saturated
  - Abnormal hemoglobin
    - Carboxyhemoglobin
    - Methemoglobin
- One can be well saturated, but have impaired oxygen delivery to tissues
- Inadequate oxygen delivery to the tissues is reflected by increased lactate production

**Relationship between Rate and PCO₂**

\[
\text{Rate} \times \text{PCO}_2 = \text{Rate} \times \text{CO}_2
\]

Assumes that Vt remains unchanged and the child is not breathing spontaneously
The Importance of Acid Base Status

7.3 ← 7.4 → 7.5

- Acidosis
  - Respiratory
    - Hypoventilation
  - Metabolic
- Effects
  - Promotes pulmonary vasoconstriction
  - Increases PVR
  - Acidosis facilitates oxygen unloading to the tissues

- Alkalosis
  - Respiratory
    - Hyperventilation
  - Metabolic
- Effects
  - Promotes pulmonary vasodilation
  - Decreases PVR
  - Alkalosis impairs oxygen unloading to the tissues

Mechanical Ventilation Strategies

- Pressure control ventilation
  - Select a peak inspiratory pressure (PIP)
    - The appropriate PIP results in adequate chest rise
  - Positive end expiratory pressure (PEEP)
  - Inspiratory time (Ti) = .75-1 second
  - Respiratory rate
    - Adjusted to normalize PaCO₂
  - Synchronized modes and pressure support should not be required
  - FiO₂ to maintain acceptable oxygen saturations

- Volume control ventilation
  - Select a tidal volume (Vt) 8-10 cc/kg
    - The appropriate tidal volume results in adequate chest rise
  - Positive end expiratory pressure (PEEP)
  - Inspiratory time (Ti) = .75-1 second
  - Respiratory rate
    - Adjusted to normalize PaCO₂
  - Synchronized modes and pressure support should not be required
  - FiO₂ to maintain acceptable oxygen saturations
  - If PIP and Paw are excessive, consider PC ventilation

Mechanical Ventilation Strategies

- Mechanical ventilation provides respiratory support for patients with respiratory failure
- Mechanical ventilation relies upon positive pressure to move air into the lungs
- Patients can be ventilated in a pressure or volume mode

Clinical Teaching Point

- Every donor should be treated as a potential lung donor
- Maintenance of tissue oxygenation and blood flow is crucial to the success of transplanted organs
- Every attempt should be made to provide adequate oxygenation and ventilation to the potential pediatric organ donor
- Despite high pressures and high concentrations of oxygen, the lungs may suffer damage in order to preserve function of other organs for transplantation
- Pulmonary blood flow can be controlled by altering pH and PaO₂ using mechanical ventilation and pharmacologic agents to improve oxygenation
**Donor Management Goals for Oxygenation and Ventilation**

- Maintain PaO2 > 100 mmHg
- Normalize PaCO2 35 - 45 mmHg
- FiO2 0.40
- Tidal volumes 8-10 cc/kg
- PEEP 5 cm H2O
- Arterial pH 7.35-7.45

---

**Treatment of Hemodynamic Instability**

- Sustained hypertension can result in deleterious effects to end organs
- Short periods of hypertension may be tolerated however long periods of hypertension can result in end organ damage
- Antihypertensive agents can help control blood pressure
  - These agents should be used cautiously as abrupt hypotension can occur from either pharmacologic treatment or cerebral herniation

---

**Hemodynamic Alterations**

- Extreme variances in blood pressure can result in end-organ dysfunction
  - Pre-herniation syndrome
    - Increased catecholamine release (catecholamine storm) results in hypertension
  - Cerebral herniation
    - Sudden loss of vascular tone results in hypotension

---

**Pharmacologic management of hypertension**

- Use short acting antihypertensive agents
  - Sodium nitroprusside (Nipride)
    - Nitroprusside with short onset and duration of action
    - 0.5-1.0 mcg/kg/min
  - Esmolol (Brevibloc)
    - Beta blocker
    - Loading dose: 500 mcg/kg
    - Infusion: 50-200 mcg/kg/min
  - Labetalol (Normodyne, Trandate)
    - Beta blocker with alpha and beta effects
    - Loading dose: 0.5-1.0 mcg/kg
    - Infusion: 0.4-1.0 mcg/kg/hour
  - Nitroprusside (Cardene)
    - Calcium channel blocker
    - Shorter duration of action with no negative inotropic effects
    - 1-3 mcg/kg/min
  - Hydralazine
    - 0.1-0.5 mg/kg up to 20 mg
    - Dosing may be repeated every 10-30 minutes

---

**Hemodynamic Alterations**

- Hypertension occurs with increased catecholamines (catecholamine storm) when herniation is occurring
  - Increasing MAP to maintain CPP
  - CPP = MAP – ICP
  - Increases SVR resulting in elevation of blood pressure
  - Leads to non-cardiogenic pulmonary edema
  - Increase in pre-load with further pulmonary edema
  - Myocardial dysfunction
  - Results in end organ dysfunction

---

**Hemodynamic Alterations**

- Sudden loss of vascular tone occurs as a result of herniation
  - Loss of adrenergic stimulation resulting in vasodilation
  - Effective volume loss resulting in hypovolemic shock
  - Vasodilation
  - Diuresis secondary to diabetes insipidus and hyperglycemia
  - Myocardial dysfunction
  - Results in end organ dysfunction
Treatment of Hemodynamic Instability

- Normal blood pressure
  - $2 \times \text{age in years} + 80$
  - Lowest acceptable blood pressure = $2 \times \text{age in years} + 70$
- Heart rate may not be a good indicator of volume status since the rate may show little variability following brain death
- Aggressive volume replacement for hypovolemia
  - Crystalloid
  - Colloid
  - Blood products

Clinical Teaching Point

- Clinical end point for titration of inotropic support for hemodynamic instability
  - Normalization of blood pressure based upon the age of the child
    - Normal systolic blood pressure: $80 + 2 \times \text{age in years}$
    - Lowest acceptable systolic blood pressure: $70 + 2 \times \text{age in years}$
  - Lower blood pressures may be acceptable if biomarkers for tissue perfusion are normal
    - Serum lactate
    - $\text{SVO}_{2}$ monitoring

Treatment of Hemodynamic Instability (cont)

- Inotropic support
  - Dopamine
  - Dobutamine
  - Epinephrine
  - Phenytoin
  - Norepinephrine
- Correction of acidosis

Cardiac Arrhythmias

- Occur secondary to:
  - Conduction system necrosis secondary to catecholamine storm resulting in medullary ischemia
  - Metabolic disturbances
  - Electrolyte disturbances
  - Inotropic agents

Treatment of Hemodynamic Instability (cont)

- Determination of volume or inotropic support to correct hemodynamic instability
  - Hemodynamic monitoring
    - Central venous pressure monitoring
    - Continuous arterial pressure monitoring
    - Pulmonary artery catheter
  - Hepatocardiac reflex

Cardiac Arrhythmias

- Treatment
  - Correction of underlying cause of the arrhythmia
  - Ventricular arrhythmia
    - Lidocaine
    - Amiodarone
    - Magnesium
  - Supraventricular arrhythmia
    - Amiodarone
  - Bradyarrhythmias
    - Secondary to vagus nerve disruption in the brain stem
    - Unlikely to respond to atropine
    - Epinephrine or isoproterenol

Serum lactate

$\text{SVO}_{2}$ monitoring
**Hormonal Replacement Therapy in Donor Management**

- Thyroid hormone
- Steroids
- Vasopressin
- Insulin

---

**Additional Considerations**

- Dopamine for hemodynamic support
  - Dopamine inhibits TSH production
  - Decreased TSH production results in decreased release of thyroid hormone from the thyroid gland
  - Further decrease of TSH from CNS insult and alteration of the HPA axis
  - Relative hypothyroid state from the CNS insult and therapy to maintain hemodynamic stability

---

**Thyroid Hormone**

- Thyroid hormone (T4) is released from the thyroid gland
- Triiodothyronine (T3)
  - Active form of thyroid hormone
  - In the peripheral circulation
  - Triiodothyronine (T3) is 4 times more active than thyroxine (T4)

---

**Thyroid Hormone Dosing**

- Thyroid hormone
  - Levothyroxine (Synthroid)
    - Route of administration: IV continuous infusion
    - Dose: 1 ug/hour titrated to effect

<table>
<thead>
<tr>
<th>Age</th>
<th>Bolus (mcg/kg)</th>
<th>Infusion (mcg/kg/hr)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-6 mos</td>
<td>5</td>
<td>1.4</td>
</tr>
<tr>
<td>6-12 mos</td>
<td>4</td>
<td>1.3</td>
</tr>
<tr>
<td>1-5 yrs</td>
<td>3</td>
<td>1.2</td>
</tr>
<tr>
<td>6-12 yrs</td>
<td>2.5</td>
<td>1</td>
</tr>
<tr>
<td>12-16 yrs</td>
<td>1.5</td>
<td>0.8</td>
</tr>
<tr>
<td>&gt;16 yrs</td>
<td>0.8</td>
<td>0.8</td>
</tr>
</tbody>
</table>

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**Effects of Thyroid Hormone**

- Thyroid hormone
  - Increases cardiac output
    - Increases intracellular calcium by increasing sarcoplasmic reticulum calcium-ATPase
    - Activation of renin-angiotensin-aldosterone axis
  - Increases heart rate
  - Increases ventilation rate
  - Increases circulating blood volume
    - Stimulation of erythropoietin production
  - Increases basal metabolic rate
  - Affects cellular metabolism
  - Up-regulates beta adrenergic receptors
  - β₁ resulted in thermogenesis

---

**Treatment of Hemodynamic Instability (cont)**

- Triiodothyronine (T₃)
  - Route of administration: IV continuous infusion
  - Dose: 0.05-0.15 mcg/kg/hour titrated to effect
  - Disadvantage: expense
Steroids

- Replace cortisol which has been inhibited by loss of HPA axis
- Up-regulate B-receptors
  - Enhance response to inotropes
- May provide an important role in stabilization of pulmonary function for the potential donor
- The use of steroids should be considered early in the course of the child with hemodynamic instability that is minimally responsive to aggressive inotropic support

Acid Base Disturbances

- Metabolic acidosis
  - Anion gap
  - Non-anion gap
  - Calculation of anion gap
    - Na\(^+\) - Cl\(^-\) + CO\(_2\)\(^\circ\)
    - Normal anion gap = 10-14
  - Anion gap
    - Uremia
    - Lactic acidosis
    - Diabetic ketoacidosis
  - Non-anion gap
    - GI losses
    - Renal wasting of bicarbonate
    - Increased CI load

- Metabolic alkalosis
  - Excessive bicarbonate administration
  - GI losses resulting in a hypochloremic metabolic alkalosis
  - Inadequate CI administration in IVF's
  - Massive blood transfusions increase citrate which breaks down to bicarbonate

Steroid Dosing

- Steroids
  - Hydrocortisone (Solucortef)
  - Route of administration: IV
  - Dose: 20-30 mg/kg IV
    - Additional doses can be administered every 8-12 hours if needed
  - Infusion: 1 mg/kg/hour administered for 12 hours (<25 kg)
  - 50 mg/hour (25-35 kg)
  - 75 mg/hour (35-45 kg)
  - 100 mg/hour (> 45 kg)

Metabolic Acidosis

- Metabolic acidosis occurs
  - Impaired oxygen delivery to the tissues
  - Increased bicarbonate losses
- Improving oxygen delivery to tissues
  - Improve cardiac output
    - Transfusion of pRBC's to improve CaO\(_2\)
    - Volume support for hypovolemia which can result in impaired cardiac output
    - Inotropic support
  - Note: Altered oxygen delivery to the tissues is reflected by an increase in serum lactate levels

Acid Base Disturbances (cont)

- Metabolic acidosis can occur because of impaired oxygen delivery to the tissues due to poor cardiac output as a result of increased PVR
  - Increased PVR results in decreased pulmonary blood flow
  - Increased PVR can result in ventricular septal bowing causing compromised left ventricular output as a result of increased right ventricular pressures secondary to PVR
  - Improve cardiac output by decreasing PVR
    - Hyperoxygenation
    - Hyperventilation
    - Inhaled nitric oxide
Controlling PVR by Altering pH and PaO₂

- Decrease PVR and increase pulmonary blood flow
  - Hyperventilation
  - Hypoxia
    - Oxygen is a pulmonary vasodilator
  - Note: Hyperventilation shifts the oxyhemoglobin dissociation curve thus altering oxygen delivery to tissues by impairing oxygen unloading
- Increase PVR and decrease pulmonary blood flow
  - Hypoventilation
  - Hyperoxia
    - Caused by pulmonary artery vasconstriction
  - Note: Hypoventilation shifts the oxyhemoglobin dissociation curve thus facilitating unloading of oxygen to tissues

GI Disturbances

- Poor perfusion to the gastrointestinal tract can result in bowel sloughing
- Fluid and electrolyte disturbances
  - Metabolic acidosis secondary to loss of bicarbonate
  - Hypokalemia secondary to fluid losses
- Treatment
  - Fluid replacement with an isotonic agent such as Lactated Ringers Solution
- Alteration of bowel flora from antibiotics can result in increased GI losses
- Alteration of the gastrointestinal mucosa can result in bacterial translocation leading to sepsis
- GI prophylaxis with H2 blockers or a PPI should be considered
- Nutritional considerations
  - If bowel integrity is intact consider enteral feedings to provide nutritional support

Metabolic Acidosis (cont)

- Increased bicarbonate losses
  - Occur through the GI tract
    - Stool wasting of bicarbonate
    - Renal wasting of bicarbonate
    - Renal insufficiency
    - Increased CI in IV fluids resulting in a hyperchloremic metabolic acidosis
  - Treatment
    - Correct the underlying cause
      - Decreased CI load in IV fluids
      - IV fluids (LR) to replace stool output
    - Sodium bicarbonate or a buffer such as THAM

Fluid and Electrolyte Disturbances

- Intravascular volume depletion can be related to the treatment of cerebral edema
- Excessive volume losses
  - Diabetes insipidus
  - Osmotic diuresis
    - Hyperglycemia
    - Glucosuria
- Hemorrhage

Pharmacologic Agents Used to Treat Acidosis

- Sodium bicarbonate
  - Dose: (1 meq/kg IV)
  - May need to adjust ventilation for CO₂ production
  - Can increase serum osmolality

- Tromethamine (THAM)
  - Dose: Base deficit x wt. kg
    - Hypoglycemia can occur in neonates
    - Contraindicated in renal failure
    - May increase coagulation time

Fluid and Electrolyte Disturbances

- Hypernatremia
  - Loss of ADH secretion results in diabetes insipidus and increased free water loss
- Osmotic diuresis
- Hyperglycemia
  - Loss of cerebral metabolism of glucose
    - Steroids
- Hypokalemia
  - Kaliuresis
- Hypocalcemia
### Treatment of Fluid and Electrolyte Abnormalities

**Volume resuscitation**

- Volume administration with an isotonic solution
  - Crystalloid
  - Colloids
  - Volume Expanders
- Dextrose containing solutions should never be used to volume resuscitate a patient

**Hyponatremia**

- Treatment: Increased free water will help to decrease serum Na⁺
  - IVF ½ or ⅓ NS
  - Free water administered via the enteral route
  - Aggressive treatment of DI with hormonal replacement therapy and replacement of urine output with ⅓ NS
  - Rapid changes in osmolarity are of little concern

**Hypernatremia**

- Treatment: KCl can be added based upon electrolytes
  - pH considerations need to be evaluated with K⁺ administration since many children will be alkalotic

**Hypokalemia**

- Treatment:
  - Limit glucose administration
  - Insulin infusion
    - Dose: 0.05 - 0.1 units/kg/hour titrated to effect
  - Follow serum glucose levels closely
Treatment of Fluid and Electrolyte Abnormalities

- Hyperglycemia
  - Glycemic control is clearly important in the critically ill patient. Hyperglycemia can have deleterious effects on end organs and has been shown to increase mortality in patients in intracranial injury.
  - Hyperglycemia can result in deleterious effect on the myocardium altering cellular metabolism.
- Treatment
  - Insulin administration
    - Enhances energy delivery to tissues and for the ischemic myocardium, it may act as a positive inotropic agent.
    - Reduces fluid losses secondary to osmotic diuresis.

Calcium Derangements

- Hypocalcemia
  - Volume replacement with colloid
    - Albumin binds Ca++
  - Massive blood transfusions
    - Citrate preservative binds Ca++
  - Sepsis
  - Infants and children have an immature sarcoplasmic reticulum which can store limited amounts of Ca++
    - Ca++ is important for muscle contraction
    - Ca++ acts as a positive inotrope to help support blood pressure.

Calcium Dosing

<table>
<thead>
<tr>
<th>CaCl²</th>
<th>Calcium gluconate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dose</td>
<td>10 mg/kg IV</td>
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<tr>
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<td>200-500 mg/kg/day IV</td>
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<tr>
<td>Route</td>
<td>Administer through a CVL</td>
</tr>
<tr>
<td></td>
<td>Can be administered through a PIV</td>
</tr>
</tbody>
</table>

- Treatment of hypocalcemia should be guided by ionized Ca++ levels
  - Maintain levels 1.0 mmol/dL
- Persistent hypocalcemia can be treated with an IV infusion of calcium chloride.

Donor Management Goals of Fluid and Electrolyte Abnormalities and Acid Base Disturbances

- Serum Na⁺ 130 - 150 meq/L
- Serum K⁺ 3 – 5.0 meq/L
- Serum glucose 60 – 150 mg/dL
- Ionized Ca++ > 1 mmol/L (if measured)
- pH 7.30 - 7.45

Neuroendocrine Abnormalities

- Loss of ADH secretion results in diabetes insipidus
  - Fluid and electrolyte disturbances
- Loss of thyroid hormone secretion
  - Alteration of hemodynamics
- Loss of adrenal function
  - Alteration of hemodynamics

Pharmacologic Agents Used for Hormonal Resuscitation (HRT)

- Thyroid hormone
  - Levothyroxine (Synthroid)
  - Triiodothyronine (T₃)
- Steroids
  - Hydrocortisone
  - Methylprednisolone
- Antidiuretic hormone
  - Desmopressin (DDAVP)
  - Vasopressin (Pitressin)
- Insulin
### DDAVP (Desmopressin)
- 1-Desamino D arginine vasopressin is a synthetic polypeptide structurally related to arginine vasopressin (ADH)
- Greater antidiuretic response on a weight per weight basis than does arginine vasopressin
- Lacks smooth muscle contractile properties as seen with arginine vasopressin
- Does not stimulate adrenocorticotropic hormone release or increase plasma cortisol levels
- Enhances platelet aggregation
- Half life of 75 - 120 mins. range of 0.4 - 4 hours

### Vasopressin (Pitressin)
- Route of administration: Intravenous
- Dose:
  - Continuous IV infusion: 0.5 milliunits/kg/hour titrated to effect
  - Note: IV dose should be avoided due to lack of cranial blood flow
- Side effects:
  - Fluid retention
  - Vasoconstriction resulting in decreased organ perfusion
  - Hypertension

### Desmopressin (DDAVP)
- Route of administration: Intravenous
- Dose:
  - Continuous infusion rate: 0.5 μg/hour titrated to effect
    - Note: Intranasal and subcutaneous administration should be avoided in this patient population
      - Intranasal route: Lack of cranial blood flow
      - Subcutaneous route: Depot effect
- Side effects:
  - Fluid/free water retention
  - Prolonged duration of action with a longer half life

### Clinical Teaching Point
- Clinical end point for treatment of diabetes insipidus
  - To decrease urine output and normalize serum sodium (130-145 meq/dl) using pharmacologic agents and fluid replacement
  - Vasopressin or Desmopressin should be titrated to decrease urine output to a manageable level (3-4 cc/kg/hour)
  - The goal is to reduce and not completely stop urine output

### Consideration for Use
- DDAVP (Desmopressin)
  - Correction of hypernatremia without hemodynamic instability secondary to greater ADH effect
  - Correction of hypernatremia with associated bleeding problems (coagulopathy)
- Vasopressin (Pitressin)
  - Correction of hypernatremia with hemodynamic instability
  - Decrease excessive urine output with a normal serum Na⁺ concentration
  - Vasoconstrictive effects may alter perfusion to organs resulting in ischemia

### Vasopressin (Pitressin)
- Polypeptide hormone (ADH) secreted by the hypothalamus and stored in the posterior pituitary (neurohypophysis)
- Vasopressin stimulates contraction of smooth muscle resulting in vasoconstriction
- No effect upon platelets
- Shorter half life of 10 - 20 minutes
Hormone Replacement Therapy

- HRT should be considered early in the course of donor management
  - Restores metabolic stability to the potential donor
  - Inhibits the anaerobic metabolism that accompanies neurologic death
  - May sensitize Beta receptors
- Stabilization of the potential donor prevents a rushed approach for recovery and allows more time for placement of organs

Causes of Coagulation Disturbances

- Acute
  - Release of tissue thromboplastin from injured brain tissue
  - May occur secondary to release of catecholamines associated with traumatic brain injury
  - Sepsis
    - Massive transfusions during resuscitation
      - Dilution of coagulation factors
      - Metabolic alkalosis secondary to the large amount of citrate that is metabolized and produces bicarbonate
      - Ionized calcium levels fall as calcium complexes with citrate which can result in hypotension
    - Shock
  - Acute liver injury
  - Alteration in production of coagulation factors from the liver
    - Acute liver injury
    - Patients with chronic liver disease

Why Start HRT Early?

- HRT is inexpensive
- Adverse effects to the potential donor are minimal
- It may increase graft function post-operatively
- Continued therapy for the dying child reinforces to the parents that everything humanly possible is being done for their child

Causes of Coagulation Disturbances

- Acute
- Drug induced
  - Heparin
  - Calcium channel blockers
  - B-Blockers
  - Antibiotics
- Uremia
- Hyper and hypothermia
- Transfusion reactions

Disseminated Intravascular Coagulation

- Widespread activation of coagulation pathways that leads to
  - Fibrin formation
  - Platelet consumption
  - Coagulation factor depletion
  - Activation of thrombolysis
- Clinical manifestations
  - Venous thromboembolism
  - Hemorrhage
  - Tissue ischemia secondary to microemboli

Causes of Coagulation Disturbances

- Acute
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  - Sepsis
    - Massive transfusions during resuscitation
      - Dilution of coagulation factors
      - Metabolic alkalosis secondary to the large amount of citrate that is metabolized and produces bicarbonate
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    - Shock
  - Acute liver injury
  - Alteration in production of coagulation factors from the liver
    - Acute liver injury
    - Patients with chronic liver disease

Disseminated Intravascular Coagulation

- Laboratory findings
  - Thrombocytopenia
  - Prolonged PT/ PTT
  - Hypofibrinogenemia
  - Elevated fibrin degradation products
  - Elevated D-dimer fragments
Diagnosis

- Bleeding
  - Wounds
  - Puncture sites
  - Gastrointestinal
  - Renal
- Laboratory studies
  - Platelet count
  - Hemoglobin
  - PT/PTT (Affected by heparin)
  - INR
  - Elevated fibrin degradation products
  - Elevated D-dimer fragments
    - Fragments are only produced when cross-linked fibrin is degraded by plasmin only
    - The action of plasmin on fibrinogen does not result in elevation of D-dimer fragments

Prevention and Treatment

- Treatment of laboratory abnormalities
  - Maintain platelet counts at least 70,000 or greater
  - May need to be more aggressive if bleeding is present or persistent
  - Platelet infusion:
    - < 15 kg: 10 cc/kg IV
    - > 20 kg: Single unit of platelets
  - INR
    - Monitor
    - Treat
    - Correction
- PT/PTT
  - Elevated
- Hemoglobin
  - Platelet
  - Renal
  - Puncture
  - INR
  - PT/PTT
  - Hemoglobin
  - Platelet
  - Renal

Treatment and Prevention

- Monitor coagulation parameters closely in any patient with traumatic brain injury or liver injury
- Treatment of the underlying disease process
  - Sepsis
  - Drug toxicity
  - Correction of hypo or hyperthermia

Prevention and Treatment

- Use of hemostatic agents to facilitate clotting should only be used in patients with known factor deficiencies.
- They can be considered for use in cases of severe uncontrolled bleeding
  - Aminocaproic acid (Amikar)
  - Factor replacement
    - Factor VII
      - Novaseven
    - Factor IX
      - Behinf
      - Binynex
      - Fopplex
  - These factor replacements can result in microemboli in potential donor tissue
  - Consultation with a pediatric intensivist is advised

Donor Management Goals for Coagulation Disturbances and Thermoregulatory Alterations

- Coagulation disturbances
  - Maintain platelet counts > 70,000
  - Normalize PT/PTT
  - Normalize INR
  - Thermoregulatory disturbances
    - Maintain core body temperature 96-99°F

Treatment of Coagulation Disturbances

- Do you really need to treat coagulation abnormalities?
  - Yes if there is significant bleeding
  - No if there is not significant bleeding
  - Depends on when you are going to surgery
Pediatric Donor Management Goals

**Hemodynamically Stable**
- Normalization of blood pressure
  - Systolic blood pressure appropriate for age
- Fluids and electrolytes
  - Normal serum lactate
  - Normal serum lactic acid
- Oxygenation and ventilation
  - FiO2 0.40
  - PaCO2 35-45 mmHg
  - Arterial pH 7.30-7.45
  - PEEP 5 cm H2O
  - Tidal volumes 8-10 cc/kg
- Thermal regulation
  - Core body temperature 96-99 °F
- Fluids and Electrolytes
  - Serum Na+ 130-150 meq/L
  - Ionized Ca++ 0.8-1.2 mmol/L
  - Serum glucose 60-150 mg/dL
- Hemodynamic support
  - Oxygen administration
  - Intravenous fluids
- Depression and sedation
  - BUP < 2 mcg/kg/hour

**Hemodynamically Unstable**
- Volume loading with crystalloids or colloids
- Inotropic support
- Dobutamine
- Dopamine
- Epinephrine
- Norepinephrine
- Steroids
- Vasopressin administration by continuous infusion

Important Area for Growth

- Pediatric DCD
  - DCD targets the two most needed organs for children
  - DCD requires extensive collaboration with the physicians, nursing staff, OR staff, OPO, and the family to ensure the best outcomes
  - Although DCD pediatric donors may be a small percentage of the entire pediatric donor pool, DCD should be considered for any child, and their family, who are facing end-of-life issues
  - Ethical issues surrounding DCD
  - Better understand issues of when a person is really dead
  - Utilize colleagues who are comfortable with this type of donation to care for and work with families who request donation
  - Work to improve understanding of all issues related to DCD

The Role of the Medical Examiner

- The medical examiner plays an important role in determining cause of death
- The ME must determine if the death was intentional versus accidental
- To accomplish this task, the medical examiner must work closely with law enforcement, investigative teams, and pediatric specialists to determine mechanism of injury
Potential for DCD to Increase Organ Donation in Children

- The potential for DCD to increase organ donation is children
  - The routine use of NHBD has the potential to increase organ donation at our institution by 42%
  - 7 additional donors and 14 additional kidneys over a 3 year period (47% consent rate assumption)

Success with DCD Organs

- Renal and liver transplants from DCD donors have graft function and transplant recipient survival rates comparable with organs recovered from SCD donors
- Lungs from DCD donors are being recovered and transplanted with good success
- 4 pediatric hearts from DCD donors have been recovered and successfully transplanted

Conclusions

- Management goals of the pediatric organ donor include:
  - Preservation of organ and tissue function
  - Restoring normal serum osmolarity and circulating volume allowing for adequate perfusion of organs and tissues
  - Prevent further organ and tissue ischemia or injury to potentially transplantable organs
  - Support for the family

Conclusions

- Children are different from adults
- Most children who die will die from a cardiac death
- Brain death does occur in children and neonates
- Brain death is a clinical diagnosis
- Care of the pediatric organ donor requires a team approach to manage the complex medical and social issues involved
UPDATED Pediatric Donor Management and Dosing Guidelines

Compiled by:
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Department of Anesthesiology
Section on Pediatric Anesthesia and Pediatric Critical Care Medicine
Wake Forest University School of Medicine
Winston-Salem, North Carolina
Formulas for Weight, ETT Size, Depth ETT, IV Fluids, and Vital Signs

Estimated Wt in kg: 2 (age in years) + 8

Estimated body surface area: \( \frac{4 \times \text{wt(kg)} + 7}{90 + \text{wt(kg)}} \)

ETT size: \( 16 + \text{age in years} \)

\( \frac{4}{90 + \text{wt(kg)}} \)

Depth of ETT (cm) = 3 x size of the ETT or 10 + age in years (children 1-12 years of age)

Lowest Acceptable Systolic Blood Pressure = (2 x age in years) + 70

<table>
<thead>
<tr>
<th>Abnormal Vital Signs</th>
<th>RR</th>
<th>Pulse</th>
<th>SBP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neonate</td>
<td>&gt; 40</td>
<td>&gt; 160</td>
<td>&lt; 60</td>
</tr>
<tr>
<td>Infant</td>
<td>&gt; 40</td>
<td>&gt; 160</td>
<td>&lt; 70</td>
</tr>
<tr>
<td>Toddler</td>
<td>&gt; 30</td>
<td>&gt; 140</td>
<td>&lt; 75</td>
</tr>
<tr>
<td>School age</td>
<td>&gt; 25</td>
<td>&gt; 120</td>
<td>&lt; 85</td>
</tr>
<tr>
<td>Adolescent</td>
<td>&gt; 20</td>
<td>&gt; 110</td>
<td>&lt; 90</td>
</tr>
</tbody>
</table>

Hypoglycemia: 2 cc/kg IV of 25% Dextrose

Hourly Maintenance fluids: 1st 10 kg = 4 cc/kg
2nd 10 kg = 2 cc/kg
>20 kg = wt(kg) + 40

Fluid Resuscitation: 20 cc’s/kg of Lactated Ringers, Normal Saline or 5% Albumin

Reassess, repeat x 2 as needed

*(Hypotonic and dextrose containing IVF’s should never be used for fluid resuscitation)*

Hetastarch (Hespan) or other artificial plasma expanders should be avoided for fluid resuscitation

(Note: Large amounts of Hepsan or artificial plasma expanders can result in a coagulopathy and should be avoided in patients with severe bleeding disorders)
# PEDIATRIC CODE MEDICATIONS

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<tr>
<th>AGE</th>
<th>NB</th>
<th>3-9 mo</th>
<th>1 yr</th>
<th>2-3 yr</th>
<th>4 yr</th>
<th>5-6 yr</th>
<th>7-8 yr</th>
<th>9 yr</th>
<th>10 yr</th>
<th>11 yr</th>
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<td>3</td>
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<td>7</td>
<td>10</td>
<td>12</td>
<td>15</td>
<td>20</td>
<td>25</td>
<td>30</td>
<td>35</td>
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<td><strong>EPINEPHRINE 1:10,000</strong></td>
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<td>Conc: 0.1 mg/cc IV</td>
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<td>Dose: 0.01 mg/kg</td>
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<td>0.7 cc</td>
<td>1 cc</td>
<td>1.2 cc</td>
<td>1.5 cc</td>
<td>2 cc</td>
<td>2.5 cc</td>
<td>3 cc</td>
<td>3.5 cc</td>
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<tr>
<td><strong>ATROPINE</strong></td>
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<td>Conc: 0.1 mg/cc IV</td>
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<td><strong>8.4% Na BICARBONATE</strong></td>
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<td>Conc: 1 meq/cc IV</td>
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<td><strong>10% Ca CHLORIDE</strong></td>
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<td><strong>ETT SIZE</strong></td>
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<td>Uncuffed ETT</td>
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<td>Depth of ETT (cm)</td>
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</tr>
</tbody>
</table>

- **Defibrillation:** 2 joules/kg. May double and repeat X 2, and then as necessary
- **Synchronized Cardioversion:** 1 joule/kg or ½ the defibrillation dose. May double and repeat X 2, and then as necessary
## Pharmacologic Agents Used for Hormonal Resuscitation

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose</th>
<th>Route</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Desmopressin (DDAVP®)</td>
<td>0.5 mcg/hour</td>
<td>IV</td>
<td>½ life 75-120 mins Titrated to decrease urine output to 3-4 cc/kg/hour May be beneficial in patients with an ongoing coagulopathy</td>
</tr>
<tr>
<td>Vasopressin (Pitressin®)</td>
<td>0.5 – 1 milli-units/kg/hour</td>
<td>IV</td>
<td>½ life 10-35 mins Titrated to decrease urine output to 3-4 cc/kg/hour Hypertension can occur</td>
</tr>
<tr>
<td>Levothyroxine (Synthroid®)</td>
<td>0.8 – 1.4 mcg/kg/hour</td>
<td>IV</td>
<td>Bolus dose 1-5 mcg/kg can be administered. Infants and smaller children require a larger bolus and infusion dose.</td>
</tr>
<tr>
<td>Triiodothyronine (T₃)</td>
<td>0.05 – 0.2 mcg/kg/hour</td>
<td>IV</td>
<td>Dose may be repeated in 8-12 hours Fluid retention Glucose intolerance</td>
</tr>
<tr>
<td>Methylprednisolone (Solu-Medrol®)</td>
<td>20 – 30 mg/kg</td>
<td>IV</td>
<td>Fluid retention Glucose intolerance</td>
</tr>
<tr>
<td>Insulin</td>
<td>0.05 – 0.1 units/kg/hour</td>
<td>IV</td>
<td>Titrated to control blood glucose levels to 60-150 mg/dL Monitor for hypoglycemia</td>
</tr>
</tbody>
</table>

Treatment of diabetes insipidus should consist of pharmacologic management to decrease but not completely stop urine output. Replacement of urine output with ¼ or ½ normal saline should be used in conjunction with pharmacologic agents to maintain serum sodium levels between 130-150 meq/L.

Hormonal replacement therapy should be considered early in the course of donor management. Use of hormonal replacement therapy may allow weaning of inotropic support and assist with metabolic stability for the pediatric donor.
# Inotropic Infusions

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milrinone</td>
<td>0.25 – 0.75 mcg/kg/min IV</td>
<td>Loading dose: 50 mcg/kg Hypotension can occur</td>
</tr>
<tr>
<td><em>(Primacor®)</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dopamine</td>
<td>2 – 20 mcg/kg/min IV</td>
<td>Titrate to desired blood pressure</td>
</tr>
<tr>
<td>Dobutamine</td>
<td>2 – 20 mcg/kg/min IV</td>
<td>Titrate to desired blood pressure</td>
</tr>
<tr>
<td><em>(Dobutrex®)</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Epinephrine</td>
<td>0.1 – 1 mcg/kg/min IV</td>
<td>Titrate to desired blood pressure</td>
</tr>
<tr>
<td>Norepinephrine</td>
<td>0.05 – 2 mcg/kg/min IV</td>
<td>Titrate to desired blood pressure</td>
</tr>
<tr>
<td><em>(Levophed®)</em></td>
<td></td>
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</tr>
<tr>
<td>Phenylephrine</td>
<td>0.1 – 0.5 mcg/kg/min IV</td>
<td>Bolus: 5 – 20 mcg/kg Titrate to desired blood pressure</td>
</tr>
<tr>
<td><em>(Neo-Synephrine®)</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vasopressin</td>
<td>0.3 – 2 milli-units/kg/min IV</td>
<td>Limited data in children. Not recommended as first line therapy.</td>
</tr>
<tr>
<td><em>(Pitressin®)</em></td>
<td></td>
<td>Titrate to desired blood pressure</td>
</tr>
</tbody>
</table>

*Note: Dosing is different for treatment of diabetes insipidus*

Inotropic agents are used for low cardiac output states to improve end organ perfusion. These agents should be titrated to maintain a normal blood pressure for age. Blood pressure alone does not indicate adequate tissue perfusion. Serum biomarkers such as lactate should be followed as inotropic support is titrated.
## Antiarrhythmic Agents

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose</th>
<th>Route</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Adenosine</strong></td>
<td>100 mcg/kg</td>
<td>Rapid IV push</td>
<td>Repeat dose: 200 mcg/kg  Max single dose: 12 mg</td>
</tr>
<tr>
<td><em>(Adenocard IV®)</em></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Amiodarone</strong></td>
<td>5 mg/kg</td>
<td>IV</td>
<td>Repeat dose: 5 mg/kg  Infusion: 5-15 mcg/kg/min</td>
</tr>
<tr>
<td><em>(Cordarone®)</em></td>
<td>infused over 5-60 mins</td>
<td></td>
<td>Monitor for hypotension</td>
</tr>
<tr>
<td><strong>Atropine</strong></td>
<td>0.02 mg/kg</td>
<td>IV</td>
<td>Min. dose: 0.1 mg  Max. dose: 0.5-1.0 mg</td>
</tr>
<tr>
<td><strong>Lidocaine</strong></td>
<td>1 – 2 mg/kg</td>
<td>IV</td>
<td>Infusion: 20-50 mcg/kg/min</td>
</tr>
<tr>
<td><strong>Magnesium Sulfate</strong></td>
<td>30 mg/kg</td>
<td>IV</td>
<td>Max. dose: 2.5 grams  Repeat dose: 10 mg/kg</td>
</tr>
<tr>
<td></td>
<td>infused over 10 mins</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Oxygenation, acid base, temperature, and electrolyte disturbances can promote rhythm disturbances and should be corrected.</td>
</tr>
</tbody>
</table>

## Correction of Metabolic Acidosis

<table>
<thead>
<tr>
<th>Compound</th>
<th>Dose</th>
<th>Route</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sodium bicarbonate</strong></td>
<td>1 meq/kg</td>
<td>IV</td>
<td>May increase plasma osmolarity  Hypernatremia can occur or be aggravated with repeated dosing</td>
</tr>
<tr>
<td><strong>Tromethamine</strong></td>
<td>Base deficit x wt(kg) = cc's of 0.3 molar solution of THAM</td>
<td>IV</td>
<td>Does not increase osmolarity or CO₂ production  Hypoglycemia can occur  Contraindicated in renal failure  May increase coagulation time</td>
</tr>
</tbody>
</table>
## Antihypertensives

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Nitroprusside</td>
<td>0.5 – 10 mcg/kg/min IV</td>
<td>Side effects include thiocyanate and cyanide toxicity</td>
</tr>
<tr>
<td>(Nipride®)</td>
<td></td>
<td>Mix 10 mg thiosulfate for every 1mg of nitroprusside</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Titrate to control blood pressure</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Monitor for hypotension</td>
</tr>
<tr>
<td>Esmolol</td>
<td>50 – 250 mcg/kg/min IV</td>
<td>Loading dose: 100 – 500 mcg/kg</td>
</tr>
<tr>
<td>(Brevibloc®)</td>
<td></td>
<td>Bronchospasm can occur</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Titrate to control blood pressure</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Monitor for hypotension</td>
</tr>
<tr>
<td>Labetalol</td>
<td>Bolus: 0.2 – 1 mg/kg IV</td>
<td>Titrate to control blood pressure</td>
</tr>
<tr>
<td>(Normodyne®)</td>
<td>Infusion: 0.4 – 3 mg/kg/hour</td>
<td>Monitor for hypotension</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nicardipine</td>
<td>1 – 3 mcg/kg/min IV</td>
<td>Titrate to control blood pressure</td>
</tr>
<tr>
<td>(Cardene IV®)</td>
<td></td>
<td>Monitor for hypotension</td>
</tr>
<tr>
<td>Hydralazine</td>
<td>0.1 – 0.5 mg/kg up to 20 mg IV</td>
<td>Dose may be repeated every 4 – 6 hours</td>
</tr>
<tr>
<td>(Apresoline®)</td>
<td></td>
<td>Monitor for hypotension</td>
</tr>
</tbody>
</table>
# Antibiotics

<table>
<thead>
<tr>
<th>Antibiotic</th>
<th>Dosage and Administration</th>
</tr>
</thead>
</table>
| **Ampicillin**      | 100 – 200 mg/kg/day IV divided every 6 hours  
Meningitis: 200 – 400 mg/kg/day IV divided every 6 hours |
| **Gentamicin**      |  
< 30 days of age: 4 mg/kg/dose IV every 24 hours  
>30 days of age: 2.5 mg/kg/dose IV every 8 hours  
    *
*Dosing adjusted based upon serum levels* |
| **Cefazolin**       | 25 – 100 mg/kg/day IV divided every 8 hours  
(Ancef®, Kefzol®) |
| **Ceftriaxone**     | 50 – 75 mg/kg/day IV/IM daily or divided every 12 hours  
Meningitis: 100 mg/kg/day IV daily or divided every 12 hours  
    *
*Use with caution in neonates because of risk for hyperbilirubenemia* |
| **Cefotaxime**      |  
< 7 days of age: 100 mg/kg/day IV/IM divided every 12 hours  
> 7 days of age: 100 – 200 mg/kg/day IV/IM divided every 8 hours  
Meningitis: 200 mg/kg/day IV divided every 6 hours |
| **Cefuroxime**      | 100 – 150 mg/kg/day IV/IM divided every 8 hours  
(Zinacef®) |
| **Ceftazidime**     | 100 – 150 mg/kg/day IV divided every 8 hours  
(Fortaz®) |
| **Clindamycin**     | 40 mg/kg/day IV divided every 6 hours  
(Cleocin®) |
| **Oxacillin**       | 100 – 200 mg/kg/day IV divided every 6 hours |
| **Vancomycin**      |  
< 30 days of age: 15 mg/kg/dose IV every 12 hours  
> 30 days of age: 40 mg/kg/day IV divided every 6 hours  
Meningitis: 60 mg/kg/day IV divided every 6 hours  
    *
*Dosing adjusted based upon serum levels* |
<table>
<thead>
<tr>
<th><strong>Transfusion Therapy</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Packed red blood cells</strong></td>
</tr>
<tr>
<td><strong>Fresh frozen plasma</strong></td>
</tr>
<tr>
<td><strong>Cryoprecipitate</strong></td>
</tr>
<tr>
<td><strong>Platelets</strong></td>
</tr>
</tbody>
</table>
Maintaining Mean Arterial Pressure in the Pediatric Organ Donor

Hemodynamically Stable

- Methylprednisolone
- Levothyroxine OR Triiodothyronine administration should be considered in this patient population
- Diabetes Insipidus
  a. Desmopressin
     1. Continuous infusion (preferred)
     2. Intermittent dose  
        OR
  b. Vasopressin administered by continuous infusion

Hemodynamically Unstable

- Volume loading with crystalloid or colloid
- Inotropic support
  - Dopamine
  - Dobutamine
  - Epinephrine
  - Phenylephrine
  - Norepinephrine
- Methylprednisolone
- Bolus dose of Levothyroxine followed by continuous infusion OR Triiodothyronine infusion
- Diabetes Insipidus
  - Vasopressin administered by continuous infusion

Desmopressin has a longer ½ life. This agent can be discontinued 2-3 hours prior to organ recovery. Consultation with pediatric intensivists and transplant surgeons should occur to discuss preferences in pharmacologic agents used to maintain hemodynamic stability.
## Pediatric Donor Management Goals

### Hemodynamic Support
- **Normalization of blood pressure**
  - Systolic blood pressure appropriate for age
  - Note: Lower systolic blood pressures may be acceptable if biomarkers such as lactate are normal.
- **CVP < 12 (if measured)**
- **Dopamine < 10 mcg/kg/min**
- **Normal serum lactate**

### Blood Pressure

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Systolic</th>
<th>Diastolic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neonate</td>
<td>60-90</td>
<td>35-60</td>
</tr>
<tr>
<td>Infants (6 months)</td>
<td>80-95</td>
<td>50-65</td>
</tr>
<tr>
<td>Toddler (2 years)</td>
<td>85-100</td>
<td>50-65</td>
</tr>
<tr>
<td>School age (7 years)</td>
<td>90-115</td>
<td>60-70</td>
</tr>
<tr>
<td>Adolescent (15 years)</td>
<td>110-130</td>
<td>65-80</td>
</tr>
</tbody>
</table>

Normal systolic blood pressure = 80 + 2 x age in years

### Oxygenation and Ventilation
- **Maintain PaO₂ > 100 mmHg**
- **FiO₂ 0.40**
- **Normalize PaCO₂ 35-45 mmHg**
- **Arterial pH 7.30-7.45**
- **Tidal volumes 8-10 cc/kg**
- **PEEP 5 cm H₂O**

### Fluids and Electrolytes
- **Serum Na⁺** 130-150 meq/L
- **Serum K⁺** 3-5.0 meq/L
- **Serum glucose** 60-150 mg/dL
- **Ionized Ca**⁺⁺ 0.8-1.2 mmol/L (if measured)

### Thermal Regulation
- **Core body temperature 36 – 38°C**
The following provides standard pediatric dosages for various pharmacologic agents used for management of the pediatric organ donor. Doses provided are guidelines only and are not intended to substitute for the medical judgment of the treating physician or transplant professional. Actual doses may vary depending on the child’s condition and other relevant circumstances.

- The management of the pediatric organ donor will be dictated by regional standards of care and the physicians caring for the child.
- Consultation with a pediatric intensive care specialist and your regional medical director is essential to ensure the best possible outcome for organ recovery.
- Become familiar with the intensive care specialists and transplant surgery guidelines in the institutions that you serve.
Authorization for Donation:

*If Only They All Said “Yes”*

Objectives

- What are the HRSA collaborative best practices on organ donation requesting processes and how can I implement them?
- How do support strategies for families of potential organ donors affect outcomes?
- What is the relevant donor demographic data from UNOS?
- How do potential ethnic and cultural differences manifest themselves in grief expression?
- What is the current literature on obtaining authorization for donation?

The Critical Organ Shortage

The tragic truth is, despite continuing advances in medicine and technology, the demand for organs drastically outstrips the number of organ donors.

A Crisis in America

- 114,812 individuals waiting for a transplant
- 28,462 organs transplanted
- 14,631 donors (living & deceased)

Reality Check

*On average, a person dies every 80 minutes waiting for an organ transplant.*
Meet Ryan

Ryan was born with a congenital heart condition.

The Problem

- In 2009, organs were recovered from 8,022 deceased donors out of an estimated 14,000 eligible deceased donors.
- 20-25% of families of eligible donors are not offered the opportunity to donate:
  - Donors are not identified
  - Families are not approached
  - Families of donor eligible African American donors are only half as likely to be offered the opportunity to donate
  - Myths still exist

Waiting for a Transplant

Like any cool kid, Ryan played video games while waiting for a life-saving heart transplant.

...the leading cause of non-donation in eligible donors?

More Than Just A Number

Like so many others, Ryan got very sick while he waited for a heart transplant. Tragically, a heart never became available for Ryan and he died waiting for a transplant.

What Builds Success?

- Expert knowledge
- Uncompromised time
- Positive attitude
- “Bedrock belief”
Factors Influencing Family Decisions

- Pt/family characteristics
  - Ethnicity, age, COD
- Prior knowledge of the deceased wishes
- OPO request patterns
  - Amount of contact with OPO
  - Person making the request
- Understanding of brain death
- Number of family members present
- Degree of satisfaction with medical care received
**Why Do Families Donate?**

- Siminoff, et al, 2007: study of 420 donor families
  - Altruism (78%)
  - Knowledge of wishes (75%)
  - Signed donor card
  - Explicit conversation
  - Confidence that donation would be patient’s preference
  - Family had positive attitude about donation (62%)
  - Coping strategy (32%)
  - Belief that the patient no longer needed his/her organs (22%)

  *But only 10% gave one reason for donating!* 

**Why Do Families Decline?**

- Reasons cited
  - Belief that the patient would not have wanted to donate (51%)
  - “Family stamina” (44%)
  - Disfigurement concerns and/or belief that donation would prevent viewing at services (43%)
  - Mistrust (25%)
  - Incorrect determination by family/team that pt not medically eligible (19%)
  - Family disagreement (14%)

**Predisposition of the Family**

- Where were they born?
- Country of origin?
- Recently immigrated?
- Long-term resident immigrant?
- Degree of acculturation?
- Do they live in an ethnic community?
- Primary language?
- Religious preference?
- Economic situation?
- Customs and beliefs?
- Observance of end of life rituals?
Utilizing The Cultural Assessment

- Assessing the degree of acculturation is more important than looking at the country of origin.
- Consider using an interpreter if:
  - English is a second language. Speaking in one's native language may be preferable during a crisis.
  - Even one family member does not speak English.
- “Huddle” with the interpreter!
- Include the religious/spiritual leader in discussions.
- Ask questions! Rituals come out at end of life.
  - “What is meaningful to your family at this time?”
  - “Please tell me about your faith/culture/etc.”

Case Study

- 2/f/hs
- Dx: head trauma from a fall
- Assessment:
  - Mother & children living in US illegally
  - Family "fostered" by Jehovah’s Witnesses
  - Spanish speaking only
- Plan:
  - Huddle w/ RN, MD, Chaplain to plan request for donation
  - Interpreter needed for end of life conversations
  - Interpreter not included in "huddle"
  - Interpreter not "pre-informed" about donation
  - Moments before family meeting, interpreter told team "Mexicans don’t donate"

Outcome? Decline

Communication via Interpreters

- “Huddle” or “pre-inform” interpreter.
- Position the interpreter slightly behind and to your side.
- Talk to the family in the first person.
- Maintain eye contact with the family.
- Consider the family’s health literacy.
- Pause frequently to allow the interpreter to interpret.

Race/ Ethnicity Characteristics

<table>
<thead>
<tr>
<th>American Indians</th>
<th>Hispanic</th>
<th>African American</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respectful distance</td>
<td>Body extremely respected</td>
<td>Respect eldest family member</td>
</tr>
<tr>
<td>Light handshake</td>
<td>Need full explanation &amp; time</td>
<td>Address as Mr. or Mrs.</td>
</tr>
<tr>
<td>Explain “WHY”</td>
<td>May understand English better than</td>
<td>Respect privacy</td>
</tr>
<tr>
<td>Value privacy</td>
<td>speak it</td>
<td>Elicit feedback</td>
</tr>
<tr>
<td>Family decisions</td>
<td>Eldest is authority figure (may wish to</td>
<td></td>
</tr>
<tr>
<td>Private mourning</td>
<td>observe BD testing)</td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td>Decisions made by whole family</td>
<td></td>
</tr>
<tr>
<td>Generally, head of family will make decisions (father or eldest son)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patriarchal society</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asian women may avert their eyes in conversation</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Urban Focused Study

Willingness To Donate

- Based on a survey of 1159 Baltimore City Residents.
- Data from Boulware E., Powe N., 2001 JHU School of Public Health
- N= 409
- Black Female
- Black Male
- White Female
- White Male

Using an Untrained Interpreter

- Request they interpret only what is said.
- Ask them to avoid holding “side” conversations with the family.
- Ask them to leave the room when you leave the room.
Crisis Is...

- A sudden and *uncontrollable* event that creates a state of complete and utter powerlessness
- A sudden and *unimaginable* event that causes physical, emotional and spiritual shock
- A sudden and *unfamiliar* event that causes a lack of orientation
- A sudden and *unstable* event that causes an imbalance and disequilibrium
- A sudden and *irreversible* event that causes an awareness of mortality

NORMAL Grief Reactions

<table>
<thead>
<tr>
<th>Reactions</th>
<th>Dependent Upon</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spontaneous crying</td>
<td>Type of death</td>
</tr>
<tr>
<td>Restlessness</td>
<td>Visual confirmation</td>
</tr>
<tr>
<td>Irritability</td>
<td>Language</td>
</tr>
<tr>
<td>Sighing</td>
<td>Culture</td>
</tr>
<tr>
<td>Obvious muscle tension</td>
<td>Legends/myths</td>
</tr>
<tr>
<td>GI disturbance</td>
<td></td>
</tr>
</tbody>
</table>
How We Die in America Today: Sudden Illness/Trauma Without Prior Co-Morbidity

- Roughly 10% of the population
- Previously healthy, living a totally normal life
- Goals of care at presentation are aggressive and curative
  - hope and possibility of cure, AND
  - concern for mortality
- Recognition of terminal state comes after a matter of hours to a few weeks

Anticipated vs. Sudden Death

**Death from long term illness**
- Anticipatory grief
- Establish EOL goals
- Meet EOL goals
- Opportunity for restitution
- Relief
- “Release” from suffering

**Sudden death**
- Intense grief (shock, denial, anger)
- Pt last seen full of life
- Feelings of senselessness
- Guilt
- Difficulty absorbing information
- No time to establish (meet) EOL goals

Professional Issues

- Hospital environment
- Skill and knowledge of the requestor
- Huddle & team approach
- Was brain death communicated in a manner conducive to the family’s understanding?

Who Is In This Population?

- **Victims of trauma:**
  - MVC, GSW, blunt trauma, falls, high percentage burn

- **Victims of acute severe medical illness:**
  - Fulminant hepatic failure
  - Fulminant sepsis and multisystem organ failure
  - Anoxic injuries
  - SAH/SDH/ICH/ruptured aneurysm
  - Acute leukemias

Organ Donation Breakthrough Collaborative

“Committed to saving or enhancing thousands of lives a year by spreading known best practices to the nations largest hospitals, to achieve organ donation rates of 75% or higher in these hospitals.”

About 50% of the nation’s eligible organ donors are in 200 large hospitals
Organ Transplant
Breakthrough Collaborative

“Save or enhance thousands of lives a year by maximizing the number of organs transplanted from each and every donor to achieve an average of 3.75 organs transplanted per donor.”

Waitlist Deaths:
Declined Over Past Two Years

Optimistic Possibility:
To Double Annual Transplants

Conversion Rate: Deceased donors/year
50% → 6,000 75% → 9,000
Organs Recovered and Transplanted: Recipients/year
3/D → 18,000 4/D → 36,000

Negative Factors
Affecting Authorization
• Feelings that loved one’s recovery was possible
• Lack of information
• Insensitivity of requestor
• Feeling rushed
• Religious objection
• Fear of disfigurement
• System unfair
• Medical Distrust

Positive Factors
Affecting Authorization
• Hospital is an advocate of organ donation
• Team huddles
• Timely notification
• Appropriate requestor
• Families satisfaction with quality of care
• Frequent communication
• Time with loved one
• Understanding of brain death
• Collaborative Best Practices

Unprecedented Month-by-Month Gains
Increases in Number of Organ Donors

Based on 2003-2004 HRSA historic statistical data
Let’s Look at the Data...

What Factors Contribute to:
Consents?
Declines?

Why Do Families Donate?
• Siminoff, et al, 2007: study of 420 donor families
  – Altruism (78%)
  – Knowledge of wishes (75%)
  • Signed donor card
  • Explicit conversation
  • Confidence that donation would be patient’s preference
  – Family had positive attitude about donation (62%)
  – Coping strategy (32%)
  – Belief that the patient no longer needed his/her organs (22%)

But only 10% gave one reason for donating!

CMS Definition: Timely Referral
• As soon as it is anticipated that a patient will meet the criteria for imminent death agreed to by the OPO and hospital or as soon as possible after a patient actually meets the criteria for imminent death agreed to by the OPO and the hospital (ideally within 1 hour).
  • AND, prior to withdrawal of any mechanical or pharmacological support

Why Do Families Decline?
• Belief that the patient would not have wanted to donate (51%)
• “Family stamina” (44%)
• Disfigurement concerns and/or belief that donation would prevent viewing at services (43%)
• Mistrust (25%)
• Incorrect determination by family/team that pt not medically eligible (19%)
• Family disagreement (14%)

Timely Referral is Critical
• Allows time to evaluate for suitability for donation.
• Assures that the family is approached ONLY if donation is determined to be a realistic opportunity.
• Allows for collaboration on the family approach.
• Increases the likelihood that the patient will be aggressively maintained so that organs will remain viable for transplantation.
**Best Practice: Team Huddles**

RN, MD, Nurse Manager, Chaplain, OPO Coordinator, Social Worker, and Palliative Care

---

**Huddle Discussion Topics**

- Who is “family”?
- When did they arrive?
- What have they been told?
- What is their understanding?
- What are their current expectations?
- Do language/cultural barriers exist?
- What resources will we need?
- When will we meet with the family?
- What is our “best plan”?

---

**Typical Team Communication Pattern**

- MD Huddle
- RN Plan
- Chaplain Plan
- OPO Huddle

---

**The Request Process**

- Preparation
- Conducive environment
- Timing
- Explanation of brain death
- A request or shared knowledge of 1st person consent
- Closure

---

**Imagine The Possibility**

- Of everyone focusing on the family...

---

**Collaborative Requests: The Team**

---
Families Need A Clear Explanation of Brain Death

- Brain death is a clinical diagnosis by a licensed physician.
- The bedside nurse may need to be coached to reinforce the brain death explanation and the clinical symptoms of brain death.
- OPO coordinators may need to explain brain death.
- Families should be supported if they request a second opinion about the brain death diagnosis.

Pearls of Brain Death Testing

- Review physiologic requirements for testing.
- Testing during daylight hours (to relieve family fatigue).
- Offer the opportunity to observe all tests.
- Review goals of the tests.
- Discuss any spinal reflexes.
- Nobody touches the patient or the bed (minimizes distracting movements).
- Maintain oxygenation during apnea testing.
- Follow-up family conference in a private setting.
- Assessment of family understanding.

AAN Practice Parameters

- 3 cardinal signs of brain death
  - Coma or unresponsiveness
  - Absence of brain stem reflexes
  - Apnea
- Confirmatory tests (optional)
  - EEG, angiography, radionuclide brain scintigraphy

Evaluating Hospital Performance Partnership for Organ Donation

- 164 Participants
  - 62% Donor Families
  - 38% Non-donor Families
- Variables:
  - Understanding of brain death
  - Timing of approach
  - Satisfaction with hospital experience
  - Conversations between staff & families

Recommended BD Documentation

- Etiology and irreversibility of condition
- Absence of brainstem reflexes
- Absence of motor response to pain
- Absence of respiration with PCO2 greater than or equal to 60 mmHg
- Justification for confirmatory test(s) and results of confirmatory tests
- Repeat neurologic exam
  - the interval is arbitrary, but a 6-hour period is reasonable

Study of Donor and Non-donor Families

% of families understanding of brain death.

What does this tell us?

- 164 NOK interviews of eligible organ donor families
- Non-donor families have apparent less understanding of BD than consenting families
**Evaluating Hospital Performance**

*Partnership for Organ Donation*

**Non-Donor Family Results**

- 47% didn’t know if BD was ever explained to them.
- 44% thought they were not given enough time to understand BD before donation was mentioned.
- 48% didn’t know if BD persons could recover.
- 40% didn’t know BD was death with heartbeat.
- 55% didn’t know BD person was not in a coma.

**Pearson, et al, 1995**

---

**Allowing Families Time to Process**

- **“Decoupling”**
  - separating the brain death explanation from the request for organ donation
- Decoupling may increase the likelihood of authorization for organ donation
- Some family members process information quickly...others take longer

---

**Communicating the Diagnosis**

- **Incongruent information for the family**
  - An “alive” looking body
  - Diagnosis of death
- **Not a stereotypical death**
- **Information sharing study**
  - 36% felt confused by the complex medical discussion
  - 55% would have preferred the use of radiographs, models, diagrams, pictures
  - All participants would have preferred being offered the chance to be present for brain death testing

---

**Hospital Staff Role in the Request**

The most obvious conflict of interest occurs when the health care team discusses organ donation with the family *before* brain death is pronounced *(Advanced Directives also at issue).*

*Leading many families to question whether the team has the best interests of the patient in mind!*

---

**Explaining The Diagnosis**

- Speak slowly and clearly
- Use simple familiar language
- Use short sentences
- Repeat information as necessary without expressing any impatience you may feel
- Your explanation may include
  - Analogies for cerebral edema (vs. soft tissue edema)
  - Use of radiographs
  - Brain models

---

**Rank Order of Next of Kin**

- Agent for the decedent
- Spouse
- Adult children
- Parents
- Adult siblings
- Adult grandchildren
- Grandparents
- Adult who exhibited special care and concern for the decedent
- Person who were acting as guardian for the decedent at the time of death
- Any person having authority to dispose of the decedent’s body

*Individual states may vary in the rank order*
The Request

Families need information about donation to make an informed decision.

Introductions

- Your name
- Who you represent
- Your role
- Offer condolences to the family
- Consider seating:
  - Allow the family to be seated first
  - If you are already seated, rise to greet them
  - Do not extend a hand to shake unless they do it first
  - SAME LEVEL POSITIONING (don’t stand over the family)
  - Consider where you sit in relation to the LNOK

Body Position & Physical Manner

- Relaxed presence.
- Arms down, palms out.
- Slow your movements.
- Lowered gaze, slight head tilt down.
- Address interviewee formally.
- Present yourself as unhurried, interested and sympathetic.
- DO NOT say you know how they feel.

Personal Preparation

- Memorize the name of the potential donor.
- Know “the story” (what has brought this family to this moment).
- Gather your thoughts; plan generally what you would like to say.
- Set the stage.
- Consider your donor family’s age, ethnicity, culture, health literacy and general expectations.

Communication Pearls

- Use phrases/language geared to family.
- Don’t emphasize the law.
- Avoid the “shopping list”.
- Describe benefits of tissue donation.
- Confidentiality of information learned.
Communication Pearls – cont’d

- Use active listening.
- Ask open-ended questions.
- Assure the family of your support regardless of their decision.
- Be honest and sincere.
- Authenticity transcends diversity.

Think Positively

- Given the opportunity to save a life, most people would do it.
- Organ donation is a meaningful thing to do.

Every Family Is Unique

- 49 y/o schizophrenic male Wiccan
- 72 y/o Indian woman from New Delhi
- 19 y/o male African American
- 7 y/o female Caucasian
- 51 y/o female Hispanic immigrant
- 71 y/o female Korean immigrant
- 49 y/o male - Jehovah Witness
- 26 y/o male – Orthodox Jew

Do barriers to donation exist?

Value-Centered Requesting

Standard Approach
- Coordinator acts as neutral counselor
- Neutral value: “I’m here to provide you with information about organ donation.”
- Passive: “Did you ever discuss organ donation with your loved one?”
- “We will support you in what ever choice you make.”
- Non-presumptive: “If you decide to donate…"

Dual Advocate
- Coordinator is an expert part of medical team
- Positive Value: “I’m here to provide you with the opportunity to donate your loved ones organs.
- Affirmative: “Most people given the chance to donate will.”
- Presumptive: “When you decide to donate…”

Never Say “Never”

2007 “senior” donor stats:
36 lungs
2 hearts
1 pancreas
662 livers
1132 kidneys

- Oldest liver donor?
- Oldest cornea donor?
- Youngest heart transplant recipient?
- Longest kidney waitlist time (uninterrupted)?

Closure

Assure every donor is carefully evaluated.
Answer final questions, concerns & myths.
Address frequently asked questions:
- Will my loved one feel pain?
- Will the donation cost anything?
- How long will this take?
- Will this affect funeral arrangements?
- Will I get to know about the recipients?

Memory-making:
- Prayer, Memory Box, Donor Medal, Hairlocks, Handprints, Brochures

Plan for final ‘good-byes’.
Risk Management Issues

- Know the Model Elements of Informed Consent.
- Follow your OPO policy on obtaining authorization.
- May have hospital staff witness family interaction.
- Clearly mark what organs and tissues family have agreed to donate on the authorization form.
- Clear, sensitive communication between the family is important and decreases the risk for miscommunication.

Family Initiated FSC Re-approach

Initial response:
21 consent
1 decline
95%

Final response:
22 consents
90%

Hospital Approach FSC Re-approach

Initial response:
14 consents
12 declines
46%

Final response:
21 consents
5 declines
81%

Who Was Asking?

FSC Approach FSC Re-approach

Initial response:
32 consents
8 declines
20%

Final response:
34 consents
6 declines
18%
Lives Saved

- Declines decreased: 21 to 11!
- 10 additional donors!
- 48% conversion rate on re-approaches!

Continuing the Dialogue:
What Works?

- Providing a positive “vision” – 4 cases
- Addressing misconceptions – 2 cases
- Early family support – 2 cases
- Continuing family support – 1 case
- Moving the conversation forward – 1 case

Discussion

Questions?
Concerns?
Comments?
Objectives

- What are the regulatory and statutory guidelines related to valid authorization for donation?
- How do recent updates to the history of the Uniform Anatomical Gift Act affect our practice?
- What is the rank order of legal next-of-kin in relation to authorization for donation?
- What are the practice implications of donor registry legislation?
- How does the CDC criteria identify high risk potential donors?

UAGA

- Who (donor) – any person > 18 or by others in the order of priority
- What – any organ tissue body part or entire body
- Why – for transplant, therapy, medical, study, research, etc.

What challenging situational experiences exist that impact authorization for donation?

UAGA

- Where (donee) – hospital, medical or dental school, OPO eye or tissue bank, cadaver procurement organization or a designated individual
- When – at the time of death
- How – without unnecessary mutilation, by a physician not responsible for health care treatment or by physicians/technicians qualified to remove the part
History of the UAGA

- 1968 – Original UAGA
  - Created the power to donate anatomical gifts for transplant, therapy, research and medical education
  - Uniformly adopted in all states
- 1987 Revision
  - Intended to up-date Act to reflect changes in circumstances and practice
  - Adopted in only 26 states
- 2006 Revision
  - Intended to strengthen the legal foundation of the donation process

What’s New?

- New definitions
- Increased focus on personal autonomy
- Rules on the role of family, friends, and caregivers
- Majority rules if there is dissent in a class
- Definition of “reasonably available”
- Health care directives requesting withdrawal of artificial support are no longer construed as a refusal to donate (default to the presumption of intent)

Strengthening the Legal Foundation for the Donation Process

The State of the States

**State Adoptions:**
- Alabama
- Arizona
- Arkansas
- California
- Colorado
- District of Columbia
- Georgia
- Hawaii
- Idaho
- Indiana
- Iowa
- Kansas
- Maine
- Michigan
- Minnesota
- Mississippi
- Montana
- Nebraska
- Nevada
- New Mexico
- North Carolina
- North Dakota
- Oklahoma
- Oregon
- Rhode Island
- South Dakota
- Tennessee
- Utah
- Virginia
- Washington
- West Virginia
- Wisconsin

**2008 Introductions:**
- Alaska
- District of Columbia
- Kentucky
- Maryland
- Missouri
- New Jersey
- New York

Why Revise the UAGA Now?

- Uneven adoption of the 1987 UAGA
- Reduced uniformity over the years by numerous amendments in each state
- State and federal laws are not in sync
- The practice of organ donation has changed significantly, including a rise in the importance of organ procurement organizations

Donor Registries

- Intent registry
  - Legislation allows persons to indicate their intent to donate, yet first person consent is not obtained
  - LNOK must provide authorization for donation
  - Donation does not occur without the authorization of LNOK
- First person consent registry
  - Individual provides authorization for donation to occur after death
  - LNOK authorization is not required
  - Focus on personal autonomy
**U.S. Donor Registries**

- 46 states & the District of Columbia have donor registries
  - 35 are run by the DMV
  - 10 are run by other entities
  - 2 states utilize the DL or donor card as the means of communicating donation decision

- 4 states do not have a registry
  - Mississippi, New Hampshire, South Carolina and Idaho
  (legislation in process)

---

**Rank Order of Next of Kin**

- Agent for the decedent
- Spouse
- Adult children
- Parents
- Adult siblings
- Adult grandchildren
- Grandparents
- Adult who exhibited special care and concern for the decedent
- Person who were acting as guardian for the decedent at the time of death
- Any person having authority to dispose of the decedent’s body

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**Authorization Form Requirements**

- Donor name
- Name & relationship of NOK
- Date & time of authorization
- NOK signature
- Witness signatures
- Permission for specific organs & tissues
- Serological testing
- Release of medical records
- Release of body for transport for donation

---

**Capacity to Grant Authorization**

- **Legal capacity to grant authorization**
  - Order of priority for NOK
  - Durable Power of Attorney

- **Mental capacity to grant authorization**
  - Comprehend information
  - Respond to and ask questions
  - Not confused or disoriented

---

**Criteria for Valid Authorization**

- Authorization is free of coercion
- Right to withdraw authorization
- Language barriers addressed (right to oral translation)
- Sufficient information to reach decision
- Explanation in terms they can understand
- Reveal probable outcomes
- Procedures explained along with complications and risks
Liability Issues

- Knowingly obtaining authorization from wrong person
- Mutilation of a corpse
- Intentional infliction of emotional distress
- Incomplete authorization form
  - If it’s not documented... it hasn’t been done!
- Inconsistence with hospital policy/procedure

Risk Management Issues

- Read and know your OPO policy on authorization
- Helpful to read the consent out loud to families
- Have hospital staff witness authorization process
- Clearly mark designated organ or tissue
- Clear communication family/OPO

An “Informed” Authorization

- General description of benefits
- ID specific organs/tissues donated
- Explanation of use/research/transplant
- General description of recovery
- Explanation of lab tests, lymph nodes, blood, cultures, access to med record
- Costs
- Impact to viewing of body

Tricky Situations

- Common law marriages
- Divorced parents
  - Who disagree
  - One parent unavailable
  - Who fail to communicate effectively
- No known LNOK/John Doe
- Minor with no LNOK
- Illegal aliens
- Ethics...ethics...ethics

Informed Processes – Cont’d

- Description of involvement of Medical Examiner & autopsy
- Transplantation may include reconstructive and aesthetic surgery
- Multiple organizations (nonprofit and for profit) may be used to facilitate the gift
- Reference to transplant abroad

Your Experiences...
**CDC Donor Exclusion Criteria**

Regardless of their HIV antibody test results, persons who meet any of the following criteria should be excluded from donation of organs or tissues unless the risk to the recipient of not performing the transplant is deemed to be greater than the risk of HIV transmission and disease (i.e. emergent, life-threatening illness requiring transplantation when no other organs/tissues are available and no other lifesaving therapies exist). In such a case, informed consent regarding the possibility of HIV transmission should be obtained from the recipient.

---

**Acceptable Pediatric Donors**

- Children over 18 months of age who are born to mothers with or at risk for HIV infection who:
  - Have not been breastfed within the last 12 months, **AND**
  - Whose HIV antibody tests, physical exam and review of med records do not indicate evidence of HIV infection

---

**Behavior/History Exclusions**

- History of the following within past 5 years:
  - Men who have had sex with another man
  - Women who were exposed to known or suspected HIV infected blood through any contact
  - Persons who trade sex for money or drugs
  - Persons who were exposed to known or suspected HIV infected blood through any contact
  - Inmates of correctional systems

---

**Laboratory & Other Medical Exclusionary Criteria**

- Persons who cannot be tested for HIV infection because of refusal, inadequate blood sample or any other reason
- Persons with repeatedly reactive screening assay for HIV-1 or 2
- Persons whose hx, physical exam, med records, high risk behaviors or autopsy reports reveal other evidence of HIV infection

---

**Pediatric Exclusionary Criteria**

- Children who meet any adult exclusionary criteria
- Children born to mothers with HIV infection or mothers who meet the behavior/laboratory exclusionary criteria for adults (regardless of their HIV status)
- Children less than 18 mos of age who born to mothers with or at risk for HIV who have been breastfed in past 12 mos

---

**Family Support**

- Bereavement support should be offered as needed/requested by families and as available by the team
- Follow-up letters about transplant recipients unless the family requests no follow-up
- Follow OPO policy/procedure
- National Kidney Foundation (NKF) Bill of Rights
### NKF Bill of Rights for Donor Families

Donor families have the right to:

1. To a full and careful explanation about what has happened to their loved one, their status and prognosis.
2. To be full partners with the health care team in the decision-making process.
3. To a full and careful explanation about the (impending) death of their loved one.
4. To opportunities to be alone with their loved one during their care or following death.
5. To be cared for in a manner that is sensitive to the families needs and capacities by specially trained individuals.

### NKF Bill of Rights Cont’d

Donor families have the right to:

6. To have the opportunity to make organ and or tissue donation decisions on behalf of themselves and of their loved one who has died.
7. To receive information suited to their needs about the need for organ and tissue donation, the process and implications for later events such as funeral arrangements.
8. To provide time, privacy, freedom from coercion, confidentiality, and the services of appropriate support persons.
9. To have their decisions respected and accepted.
10. To have opportunity to spend time alone with their loved one before or after the donation process and to say their goodbyes with respect to cultural and religious beliefs.

### NKF Bill of Rights Cont’d

Donor families have the right to:

11. To be assured their loved one will be treated with respect.
12. To receive timely notification as to which organs/tissues were or were not removed and why.
13. To receive timely notification as to how any donated organs/tissues were used.
14. To be assured the donor family will not be burdened with any expenses arising from organ/tissue donation.
15. To receive ongoing bereavement follow-up support for a reasonable time period.
Discussion
Questions?
Concerns?
Comments?
Donate Life...Full Circle

RESEARCH

Research Organizations

Work as a Team with the OPO and the researcher
- facilitate placement of “non transplantable organs/tissues”
- identify new sources of donations
- expand potential donor pool
- assess research needs

Considering Consent

• When transplantation is not an option, solace can still be found through–
• A chance to save thousands of lives through new medical discoveries
• The opportunity to contribute to studies on diseases affecting their own loved ones

Speaking with Families: Consent

• Research is an option for every family. Research consent is on every consent form.
• Informed consent
  - Provide placement information
  - Your comfort level matters
  - Provide image
  *PROFIT/NON-PROFIT

Increasing Outcome Measures

“In this final rule, we establish 3 outcome measures for OPO’s:
1) Donation rate; 2) Observed donation rate compared to the expected donation rate, as calculated by the SRTR; and
3) A yield measure for both organs transplanted per donor and organs used for research per donor

Fulfilling a Wish...

• Research donation provides additional options for the donor family
  - placed vs. discarded
  - research may directly support medical issues with the donor/donor family
• Most families feel satisfaction that their loved one can contribute to medical science if transplant is not possible
• Research is the Gift of HOPE!
**Benefits of Research Placement**

**Should I call?**

- Fulfill donor family wishes
- Advancement of Medicine in all fields
  - surgery
  - pharmaceuticals
  - transplant technology
  - education

---

**The Face of Research**

**Benefits of Research - Lung**

---

**New Outcome Measure; 2007**

CFR 42 486.318

- “a yield measure for both organs transplanted per donor and organs used for research per donor”
  - “used” for research – CMS will consider any organ that an OPO sends to an individual or organization for research purposes
  - Definition being refined by AOPO steering committee – IIAM and NDRI participating
  - Questioning pre/post recovery “qualifications”

---

**Which Organs/Tissues Can be Donated to Research?**

- Vital perfused organs (organ donors)
- Specimens
- Soft tissues (organ & tissue donors)
- Non-transplantable bone/skin
- Anatomical Gift of Body
  - some programs allow for whole body donation for organ & tissue donors
  - check into pre-registration requirements

---

**Research Helps Real People...Today and Tomorrow.**

**Benefits of Research - Lung**

---

**Potential Research Donors**

- The Extended criteria donor
  - UNOS definition
    - >60 years of age, or
    - 50-59 yrs of age with
      - (2) Hx HTN, COD is CVA, Creat > 1.5
    - HX ETOH/Smoking
    - Biopsy results
  - Anatomical anomaly
  - Unexpected Malignancy in OR
  - DCD
  - Elevated Labs
  - Limited recipient list
    - ABO
    - *size
    - Split liver
Acceptance Criteria
Does it matter if it's for research?

Variables affect the study
✓ Serologies
✓ Fat content
✓ Biopsy
✓ CT/WIT
✓ Viable Cells
✓ Donor med/soc history
✓ Anatomy (pump studies)
✓ Damage
✓ Vasculature

All data matters!

Renal Research
• Advancement in renal assist devices
• Treatments in polycystic kidney disease
• Studies on cell based therapy for renal failure

Solid Organ Research

<table>
<thead>
<tr>
<th>Organ</th>
<th>Hours post cross clamp to Delivery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bladder</td>
<td>24</td>
</tr>
<tr>
<td>Heart</td>
<td>15-24</td>
</tr>
<tr>
<td>Intestine</td>
<td>16-24</td>
</tr>
<tr>
<td>Liver</td>
<td>24</td>
</tr>
<tr>
<td>Lung</td>
<td>15-24</td>
</tr>
<tr>
<td>Kidney</td>
<td>24</td>
</tr>
<tr>
<td>Pancreas</td>
<td>8-12</td>
</tr>
<tr>
<td>Stomach</td>
<td>24</td>
</tr>
</tbody>
</table>

Pancreatic Research
• T1D Research
• T2D Research
• Pediatric <10 yrs.
• Gestational Diabetes Research
• Islet cell isolation and transplantation

Factors Affecting Bio-specimen Retrieval and Distribution

– National issues
  • Reduced NIH funding
  • More organs utilized for transplant
  • Research quality equal to transplant

– Research Trends
  • Fewer tissues & smaller sample sizes needed
  • More fresh tissues requested
  • Multiple preservation methods requested
  • Shorter hours post-mortem intervals
  • Technically complex dissections
  • More diseased tissues
  • Matched donors
  • Detailed medical histories required

Pulmonary Research
• New treatment for cystic fibrosis
  • CF is the most common hereditary disease in the US
• And to develop treatments for
  • asthma
  • rhinitis
  • COPD
Hepatic Research

- Hepatocyte isolation and transplant clinical trials
- Study effects of drugs, carcinogens, and toxins
- Study of drug induced changes in genes
- Hepatitis C studies

Ocular Research

- Studies in Glaucoma, Cataracts, Retinitis, AMD, and Diabetic Retinopathy
- Study on the pharmacology of the central endothelium which is responsible for maintaining corneal nutrition

Cardiac Research

- Develop drugs to improve treatment and safety
- Provide human cardiac tissue to test drug effects on the human heart.
- Investigations of cellular changes that may contribute to heart failure
- Studies on electrochemical effects of cardiac medications

Skeletal Research

- Development of footwear for diabetics that will reduce amputation
- Investigate age-related changes in the damage of human cortical bone
- Understanding the role of genes in the destruction/repair of cartilage in order to treat arthritis

Skin Research

- Research in how heavy metals permeate skin
- Trans-dermal drug therapies
- Studying drug toxicity and drug metabolism
- Recovery of stem cells from hair follicles
- IPS Cells

Recovery

- All vital organs (liver, kidney, pancreas, heart, lungs, intestines)
- Non-traditional recoveries: stomach, spleen, adrenals, thyroid, bladder
- Recovery protocols have been established
- Recovered by surgeon or trained staff
Recipients of Research Tissue

- Approved scientist applicants through IRB or Scientific review committee
- Non-profit/profit agencies
- Respect the gift

You should know...

✓ Researchers establish criteria based on their study needs (variables)

✓ Researcher availability changes
  - frequency of needs
  - intake/volume
  - study grant funding
  - weekend/holiday

New Research Needs

Non-traditional recoveries
- Bladder (several per week needed)
- Stomach
- Adrenals
- Bone Marrow
- Muscle tissue

How you can help
- Discuss projects with families to obtain consent
- Keep in touch with your research partner to keep up to date on active projects

Current Research Projects...

- Preservation pumps and solutions
- COPD, Asthma, CF
- Diabetes 1/2
- Environmental toxicities
- Metabolism and absorption studies

Remember...

- Cancer
- Safe drug development
- Coronary plaque studies
- Incontinence
- Islet cell & hepatocyte transplantation

The Waiting List...

26 million asthma sufferers
3 million w/ emphysema
17 million diabetics
12 million w/ heart disease
30,000 children and adults with CF
20 million suffer from arthritis
10 million osteoarthritis (80% women)
Be a hero!

When a donor organ can not help the thousands of people who are waiting for a transplant....

...remember the millions who die every day waiting for a cure.

Questions?

Thank You!

“The greatest gift is a portion of thyself...”

Ralph Waldo Emerson
Tissue Donation and Transplantation

- Autograft
- Prosthetics
- Xenograft
- Allograft

- From same species (donor)
- Advantages
  - High quality
  - No 2nd operative site
    - Decreased pain and morbidity
    - Decreased operative time
  - Versatility
    - No anti-coagulants
- Disadvantages
  - Limited supply
  - Chance of rejection
  - Risk of disease transmission
  - Slower, less complete healing; mostly osteoconductive

- Over 36 Million Americans have Musculoskeletal disorders
- Over 1.2 Million Tissue Grafts are transplanted each year (aatb)
- Over 70,000 Heart Valve Replacement Surgeries take place each year.
- Over 55,000 Corneas are transplanted each year.

- Limited Supply – public & hospital awareness
- Rejection – immunogenic cells removed during processing
- Disease Transmission
  - FDA oversight
  - Strict screening protocols
  - Most sensitive serologic testing
  - New process technologies
What Can Be Donated?

- Bone, cartilage, tendons, fascia, pericardium
- Heart for Valves
- Blood Vessels
- Skin
- Eyes for Corneas, Sclera
- Corneas

American Association of Tissue Banks
- Established in 1976
- Began Accreditation 1985
- Set Standards
- Voluntary Membership

Typically, No
- Prosthetics are Used
- Body is completely restored
  - Full Thickness skin

1990’s report of HIV Transmission to the CDC
- Fresh Frozen Grafts
- 1993, Reports of Importation of human tissue not properly screened.
- December 1993, Interim Rule
- Final Rule 21 CFR Part 1270
- Good Tissue Practices, May 2005

Organs vs Tissues
- Tissue is highly regulated
- Organ Donation is not regulated, except organ placement.

Clinical Uses of Allograft

Musculoskeletal
- Orthopedic surgeons
- Neurosurgeons
- Plastic surgeons
- Maxillofacial surgeons
- Periodontists
- Dentists

**Osteosarcoma**
- Most common bone neoplasm
- Adolescent years
- Sites
  - Distal femur
  - Proximal humerus
  - Proximal tibia

**Treatment Alternatives**
- Amputation
- Replacement with:
  - Prosthetic
  - Osteoarticular allograft

*Figure 1b: Defect site after filling with 4.5mm plugs.*
Traumatic Injuries

Intact ACL

Torn ACL

Bone-Tendon-Bone (Patellar Tendon)

Achilles Tendon w/bone block

Bone/Tendon/Bone
Kneecap
Anterior Tibialis
**Normal Disc**

**Degenerated Disc**

---

**CORNEAL TRANSPLANT**

- Corneal transplants
- Indications
  - Disease
  - Injury
  - Infection

---

**FRA Spacer**

---

**CLINICAL APPLICATIONS**

- Superficial peritoneal
- Epiploica
- Peritoneum
- Omentum
- Subcutaneous tissue
• Split thickness skin grafts (STSG)
  — Processed fresh or cryopreserved
  — Used for burn patients
• Acellular dermal skin grafts
  — Thicker dermal recoveries
  — Epidermis and cellular material removed
  — Multiple surgical applications

• Biologic Dressing for Burns
  — Temporary covering, rejected in 7-10 days
  — Prevents loss of fluids, heat and proteins
  — Prevents infection

• Bladder sling procedure
• Pelvic floor reconstruction
• Dural patch graft
• Breast reconstruction
• Rotator cuff repair
• Hernia repair

• 4-year old conjoined twin girls, Kendra and Maliyah Herrin
• Separated and reconstructed on August 7th and 8th
• Joined at the torso, they shared a pelvis, bladder, large intestine, a fused liver and one kidney
• Each will need a prosthetic leg. Maliyah will need a kidney transplant in the near future.

• Surgeons inserted 22 tissue expanders under the skin on June 23rd in preparation for the separation
• 26 hour surgery to separate and reconstruct
• Multiple teams of surgeons involved
  — Pediatric surgeons (2)
  — Anesthesiologists (2)
  — Plastic surgeons (2)
  — Pediatric urologists (2)
  — Pediatric orthopedic surgeons (2)
  — Radiologist
  — 30 support staff

• Consultant ordered 109 pieces of tissue.
• Used 14 pieces of tissue (total) to provide support under the stretched skin. It was used to cover the organs and replace missing fascia before closing the outer skin.
**Full Thickness Skin**

A brief introduction

- Treatment of large defects
  - Following Cancer
  - Abdominal Hernia
  - Trauma repair

**CARDIOVASCULAR**

- Types of Vascular Tissues
  - Patch grafts
  - Saphenous vein
  - Deep femoral vein
  - Aortoiliac artery
- Indications
  - Peripheral vascular bypass
  - Coronary artery bypass
• Valve types
  — Aortic
  — Pulmonary
• Valve replacement surgeries
  — Pediatric
  — No anti-coagulants

- Allografts are safe & viable options in a multitude of different clinical uses
- Advances in the processing of allografts will increase their use in the future

Thank you
Donor & Recipient Histocompatibility
the organ and tissue recovery process

Jonah Odim
NATCO Introductory Education Course, Tempe, Arizona, June 16, 2012

The speaker declares no competing financial interests or conflicts of interest
Email: odimj@niaid.nih.gov
for copies of slides and/or questions

Solid Organ Transplantation
Long-term failure

Graft Survival (%)
1-year  3-year  5-year  10-year
Kidney  92  82  68  38
Heart  87  79  68  48
Lung(s)  82  58  49  -

Solid Organ Transplantation
Short-term success

<table>
<thead>
<tr>
<th>Organ</th>
<th>1-year graft survival (%)</th>
<th>1-year patient survival (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kidney</td>
<td>92</td>
<td>96</td>
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<tr>
<td>Liver</td>
<td>82</td>
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<td>Heart</td>
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<td>Pancreas</td>
<td>78</td>
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<tr>
<td>Lungs</td>
<td>82</td>
<td>84</td>
</tr>
<tr>
<td>Small Intestine</td>
<td>78</td>
<td>84</td>
</tr>
</tbody>
</table>

HEART TRANSPLANTATION
Actuarial Survival (1/1982-6/2005)

Persisting Pester Problems

- Supply/demand imbalance
- Chronic rejection and graft loss
- Renal and cardiovascular morbidity
Objectives

- Immunology relating to transplantation
- Histocompatibility testing (ABO, HLA, PRA, Crossmatch)
- Measuring antigen differences between donor and recipients
- Immunologic risk assessment

Transplant Rejection
The Basics

ABO compatibility and organ selection

- ABO identical or compatible
- UNOS regulations
- Organ type (liver vs. the other organs)
- A2
- Permissible mismatches follow the same rules established for blood transfusion

Role of immune system

- Defense against invading organisms
- Surveillance
- Distinguish self from non-self (recognition)
- Proliferation and differentiation of responders (activation)
- Protective response (effector)
- Mop and clean up duty/patrol

Immune system

- Innate (non-specific) immunity
  primitive
- Adaptive (specific) immunity
  sophisticated
The Basic Lexicon

- allograft (vs. xenograft)
- alloantigen
- alloimmune response

The Basic Players

- Human Leukocyte Antigens (HLA)
- Antigen-Presenting Cell (APC)
  - Dendritic Cells
  - T & B Lymphocytes

MHC class I molecules

- all nucleated cells
- HLA-A, -B, -C (chromosome 6)
- presents antigen from inside cells (e.g. virus)
- recognized by CD8+ cytotoxic T cells

MHC class II molecules

- Only in certain cell population (APCs, B cells)
- HLA-DP, -DQ, -DR (chromosome 6)
- presents antigen from outside cells (e.g. bacteria)
- recognized by CD4+ helper T cells
**HLA - Recap**

- Presents foreign peptides to T cells
- **Class I** (on all nucleated cells)
  - present 'endogenous' antigens
- **Class II** (on APCs)
  - present 'exogenous' antigens
- Degree of HLA matching correlates with long-term graft survival
- Rejection can occur despite 'perfect' HLA matching (MHC)

**Panel of reactive antibodies (PRA)**

- recipient's serum
- panel of lymphocytes
- 50% PRA

**Panel Reactive Antibodies (PRA)**

- test for acquired antibodies
- reduces risk of hyperacute rejection
- performed monthly; 1-2 day turn-around
- complement-mediated lysis of panel of lymphocytes using recipient serum
- none killed = 0%; all 40 killed = 100%
  - normal male = 0%
  - normal female = 0-100%

**Elevated PRAs**

- pregnancy/multiple fathers
- transfusions
- SLE, other autoimmune disease
- drug/microbe cross-reactivity
- prosthetic devices (LVAD)
- Surgery with homograft placement
- may be treated with IV Ig, *Cytoxan*, plasmapheresis, *Rituximab* = desensitization

**Why do PRAs “decrease”?**

- transient antibody production
- maturation of antibody response
- cross-reactivity induced by drugs or other circulating molecules
- change in PRA panel of lymphocytes
- change in reagents or assay
- desensitization treatment
- false positive (lab glitch)
**PRA: practical points**
- Results are dependent on the panel of test lymphocytes
  - Limited sampling
  - Typically represents the local population
- PRA > 10% is associated with an increased risk of hyperacute rejection
- PRA = 0% does NOT preclude the possibility of hyperacute rejection
- PRA values are NOT predictive for acute or chronic rejection
- PRA is NOT the same as ABO testing

**PRA: limitations as measure of sensitization**
- No consistency in panels used to define PRA
- Panels not representative of donor population (inclusion of rare HLA phenotypes)
- PRA applied differently among transplant centers (list peak or current PRA values)

**Calculated PRA**
- October 2009 extra allocation points to sensitized patients based on CPRA
- New policy change for national renal organ allocation
- Eligibility for extra 4 pt award
  i) PRA > 80
  ii) Negative cross-match with the potential donor
- CPRA is based on unacceptable antigens listed for patients (The CPRA is calculated from HLA frequencies [HLA-A, HLA-B, -DR and -DQ] of listed unacceptable antigens)

**PRA limitations (2)**
- PRA could only be determined for HLA class I or class II antigens, but not both (underestimates degree of sensitization)
- Emergence of more sensitive solid phase immunoassays (SPI) led centers to apply PRA unequally (these assays can detect Ab levels beneath the threshold of cross-match assays giving candidates who were listed with PRAs > 80 using SPI an unfair advantage)

**Future considerations**
- Add additional HLA frequency data (e.g., HLA-C and -DP antigens)
- New OPTN policy requiring molecular typing of deceased donors
- Desensitization and removal of unacceptable antigens may lead to loss of allocation points. Consideration of a sliding scale of CPRA points rather than an absolute threshold of a minimum CPRA value for awarding extra allocation weight is under consideration
**Cross matches**

- **Cross match: complement-mediated cytotoxicity**
  - Host antibodies
  - Donor lymphocytes
  - Complement
  - Killed cells

- **Cross match: flow cytometry**
  - Host antibodies
  - Donor lymphocytes
  - Fluoresceinated anti-Ig
  - Fluorescence intensity
  - Negative
  - Positive

**Cross matches: practical points**

- Donor T cells are used to look for antibodies to MHC class I
- Donor B cells are used to look for antibodies to MHC class II
- Peripheral blood cells are used in living-related donors
- Lymph node or spleen is preferred for cadaveric donation
  - Better B cell yield
  - Fewer transfusion and drug effects

**Evolution of HLA Ab testing**

The need for both sensitive and specific HLA antibody identification methods

**Solid phase immunoassays (SPI)**

**Solid phase assays**

**Methods**

- Enzyme-linked immunosorbent (ELISA)
- Fluoro-analysis beads

**Targets**
- Soluble HLA molecules
  - Pooled antigens
  - Panel of phenotypes
  - Panels of single antigens with class I and II separated
Solid phase assays

These new sensitive, specific, analytic tools have provided the community with new toys and tools and CHANGED how we interpret cross-match results.

Challenges and conundrums

- lack of standardization of testing procedures and commercial kits (median fluorescence intensity [MFI] showed a 3 fold difference [2000 – 9000] between 8 labs on 2 continents using the same method to test identical serum)

How can one then correlate antibody strength (titer) with crossmatch result (+ or -) let alone with clinical outcome?

Challenges and conundrums

- Antigen expression (density) on the bead or cellular target are not uniform from batch to batch within the same platform

- Antibody function (beyond just binding) are important in ultimate correlation to clinical outcome

PRA and cross matches

- PRA screens for the presence of preformed antibodies against a panel of leukocytes bearing different HLA molecules

- Cross match looks specifically for the presence of pre-formed antibodies against only the HLA on a potential donor
  - performed when PRA >25%
  - or presence of “called antigen”
  - or previous hyperacute rejection

Histocompatibility and the assessment of immunologic risk

Factors affecting immunologic risk

Recipient

- Presence of DSA
- History of sensitization
- Previous early rejection
- High sCD30 levels
- High responder cytokine genotype
- African American race

all increase risk
Factors affecting immunologic risk

Donor
- Deceased donor
- Long cold ischemia time
- Increased numbers of HLA mismatches (above increase risk)

Living donor
- Good HLA match
- Mismatches are “acceptable” (decrease risk)

Factors affecting immunologic risk

Immunosuppression
- Induction therapy
- Desensitization
- Cell-depleting therapies

all decrease risk

Tissue Typing: matches vs. mismatches

zero-antigen mismatch but a five-antigen match
Donor: HLA-A2, - Recipient: HLA-A2, A3
HLA-B5, B8 HLA-B5, B8
HLA-DR3, DR7 HLA-DR3, DR7

Because blanks are most commonly due to homozygosity of a given antigen, the numbers of mismatches is a better predictor of survival than the numbers of matches, and increases the numbers of patients getting well-matched grafts

Avoid mismatches

Tissue Typing: reasons for a “blank” in HLA typing

- failure to detect a rare antigen because of lack of the appropriate typing antibodies (infrequent)
- technical glitch (infrequent)
- homozygosity for a particular antigen; that is both the HLA-A (or HLA-B, or HLA-DR) alleles are the same for a given person

“blanks” are generally assumed to be due to homozygosity

Tissue Typing: matches vs. mismatches

one-antigen mismatch, five-antigen match
Donor: HLA-A2, A3 Recipient: HLA-A2, -
HLA-B5, B8 HLA-B5, B8
HLA-DR3, DR7 HLA-DR3, DR7

The recipient here is assumed to be homozygous for A2

The donor now has one antigen (A3) which the recipient doesn’t have

Avoid mismatches

HLA tissue typing
### Tissue Typing: finding the best match

Assume all the same blood group:

<table>
<thead>
<tr>
<th>Recipient: A2, A30</th>
<th>B18, B50</th>
<th>DR7, DR15</th>
</tr>
</thead>
<tbody>
<tr>
<td>Donor X: A2, A29</td>
<td>B20, B50</td>
<td>DR7, DR15</td>
</tr>
<tr>
<td>Donor Y: A2, A30</td>
<td>B16, B51</td>
<td>DR5, DR15</td>
</tr>
<tr>
<td>Donor Z: A2, A29</td>
<td>B27, B44</td>
<td>DR7, DR13</td>
</tr>
</tbody>
</table>

Donor W: A5, A29  B20, B51 DR5, DR17

#### Assume all the same blood group:

<table>
<thead>
<tr>
<th>Recipient: A2, A30</th>
<th>B18, B50</th>
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</tr>
<tr>
<td>Donor Z: A2, A29</td>
<td>B27, B44</td>
<td>DR7, DR13</td>
</tr>
</tbody>
</table>

- **2 antigen mismatch**
- **3 antigen mismatch**
- **4 antigen mismatch**
- **6 antigen mismatch**

#### Survival of cadaveric renal allografts vs. mismatch number (41,000 pts)

<table>
<thead>
<tr>
<th>Number of HLA-A, -B, or -DR mismatches</th>
<th>10 year survival (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>50%</td>
</tr>
<tr>
<td>1</td>
<td>44%</td>
</tr>
<tr>
<td>2</td>
<td>43%</td>
</tr>
<tr>
<td>3</td>
<td>41%</td>
</tr>
<tr>
<td>4</td>
<td>38%</td>
</tr>
<tr>
<td>5</td>
<td>33%</td>
</tr>
<tr>
<td>6</td>
<td>29%</td>
</tr>
</tbody>
</table>

- Transplant recipients can lose their grafts even with no mismatches
- Transplant recipients can keep their grafts even with six mismatches

### Tissue Typing

- **Identifies which HLA molecules are on the surface of donor or recipient cells**
- **Performed using characterized “typing antibodies” with known specificity (e.g., HLA-A2), or using DNA molecular probes against unique genetic sequences**
- **Most labs report only HLA-A, -B, and -DR; HLA-C, -DP, and -DQ are less important**
- **Reported as e.g., A2,3; B8,44; DR 3,4 (remember: two HLA molecule sets, one from each parent)**
- **Occasionally get only a single antigen, or a “blank” at one of the loci, e.g., A2,-**
Tissue Typing

- better HLA matches (fewer mismatches) improves the survival of a graft
- especially important for bone marrow transplantation (to prevent graft-versus-host disease)
- less important in solid organ transplantation, especially with current immunosuppression
- However, still an important consideration where organ will come from a living-related donor
- And, important for retrospectively evaluating graft survival statistics

The future of crossmatching – going virtual?

New immunosuppressive strategies
Desensitization (antibody reducing) protocols
  - High dose IVIG
  - Plasmapheresis
  - Splenectomy
  - Rituximab
  - Bortezomib (proteosome inhibitor) & other emerging cell-depleting agents to overcome immunologic barriers

Cases at 2 am

Case-1: A2 kidney for O recipient with anti-A titer > 1:64 (high)

Choices:
1) Accept
2) Decline
3) Desensitize

Case-2: A1 liver for fulminant O recipient

Choices:
1) Accept
2) Decline
3) Desensitize

Case-3: HLA complete mismatched SCD (standard criteria donor) kidney for recipient: CDC XM, Flow XM, DSA all negative

Choices:
1) Accept
2) Decline
3) Desensitize

Cases and questions?
Cases at 2 am

Case-4: HLA complete mismatched SCD (standard criteria donor) kidney for recipient: CDC B cell XM +, Flow XM -, DSA -
Choices:
1) Accept
2) Decline
3) Desensitize

Cases at 2 am

Case-5: HLA complete mismatched SCD (standard criteria donor) kidney for recipient: CDC B cell XM +, DSA Class II +, Flow XM -
Choices:
1) Accept
2) Decline
3) Desensitize

Cases at 2 am

Case-6: HLA complete mismatched SCD (standard criteria donor) kidney for recipient: CDC T cell XM + before heat, negative after heat, DSA negative
Choices:
1) Accept
2) Decline
3) Desensitize

Histocompatibility
Lessons Learned

Refused to learn from my mistakes

Questions for review

Q-1 Serologic tissue typing before kidney transplantation reveals that the leukocytes of a prospective recipient are killed by the following anti-HLA antibodies in the presence of complement: anti-B27, anti-A1 and anti-A3. Which of the following statements can be concluded from the results?

Q-1 Choices

A) The prospective recipient expresses the B27, A1, and A3 HLA specificities
B) The prospective recipient does not express B27, A1, and A3 specificities
C) Potential donor and prospective recipient are not siblings
D) Potential donor and prospective recipient are not identical twins
E) Prospective recipient should not receive a kidney allograft that expresses these HLA specificities
Q-1 Answer
A) The prospective recipient expresses the B27, A1, and A3 HLA specificities.

Findings are the result of a lymphocytotoxicity test. Killing of cells following incubation with MHC-specific antibodies and complement indicates the expression of the MHC antigens for which the antibodies are specific, in this case, MHC class I determinants B27, A1, and A3.

E) is incorrect because we have no information about the recipient's MHC antigens to guide this decision.

Q-2
In clinical transplantation, preformed cytotoxic antibodies reactive against MHC antigens expressed on the grafted tissue cause:

A) Chronic rejection
B) Hyperacute rejection
C) Acute rejection
D) Delayed-type hypersensitivity
E) No serious problem

Q-2 Answer
B) Hyperacute rejection

Hyperacute rejection is caused by preformed cytotoxic, complement-fixing antibodies that cause platelet activation and deposition, leading to swelling and hemorrhage in the transplanted tissue. This quickly leads to decrease in blood flow through the tissue and ultimate rejection of the graft.

Q-3 Answer
B) Genes that encode immunoglobulins

The MHC contains all genes mentioned except genes that encode immunoglobulins.

Q-4
Which of the following statements regarding GVH disease is incorrect?

A) GVH can result from MHC differences between donor and recipient
B) GVH requires immunocompetent donor cells
C) GVH may result from infusion of blood products that contain viable lymphocytes into an immunologically incompetent recipient
D) GVH requires natural killer cells
E) GVH may occur in an immunosuppressed individual

Q-3
The MHC contains all of the following except which?

A) Genes that encode transplantation antigens
B) Genes that encode immunoglobulins
C) Genes that regulate immune responsiveness
D) Genes that encode some components of complement
E) Genes that encode class I and class II antigens
Q-4 Answer

D) GVH requires natural killer cells

GVH disease is caused by the destruction of cells or tissue of an immuno-incompetent recipient by immunocompetent lymphoid cells transferred from a histoincompatible donor. The GVH reaction does not require natural-killer cells

Q-5

Graft rejection may involve:

A) cell-mediated immunity
B) Type III (immune complex) hypersensitivity
C) Complement-dependent cytotoxicity
D) The release of IFN-γ by alloreactive TH 1 cells
E) All of the above

Q-6 Answer

B) MHC class I molecules are expressed on nearly all nucleated cells, but constitutive expression of MHC class II molecules is limited to APC such as B cells and dendritic cells. MHC class II expression can be induced on other cell types such as endothelial cells and fibroblasts by cytokines

Q-6

All of the following are characteristic of both MHC class I and class II molecules except:

A) They are expressed codominantly
B) They are expressed constitutively on all nucleated cells
C) They are glycosylated polypeptides with domain structure
D) They are involved in presentation of antigen fragments to T cells
E) They are expressed on the surface membrane of B cells

Q-7

MHC class I molecules are important for which of the following?

A) Binding of CD8 molecules on T cells
B) Presenting exogenous antigen (e.g., bacterial protein) to B cells
C) Presenting intact viral proteins to T cells
D) Binding to CD4 molecules on T cells
E) Binding Ig on B cells
A) The interaction of CD8 expressed on the T cell and an invariant region of an MHC class I molecule expressed on an antigen presenting cell or target cell tightens the interaction between the two cells and plays a critical role in the triggering of CD8+ T cells.
Why are you here?

- To receive basic instruction on the recovery of organs and tissue for transplantation.
- The gain knowledge and skills that will promote high standards of quality in organ and tissue procurement, preservation and distribution.
- Along with the ultimate goal of promoting increased organ and tissue donation and to accelerate the recovery of organs and tissue for transplantation.
- Earn CEs

Objectives

- What is the role of the OPTN and how does it affect my practice?
- How does the role of UNOS interface with donation and transplantation?
- What is the process for UNOS policy development and how can I participate?
- What are the main applications in the UNOS computer system?
- How do key policies drive decisions in real-life situations?

OPTN/UNOS - Introduction

National Organ Transplant Act (NOTA) - 1984
- Established the Organ Procurement and Transplantation Network (OPTN) to maintain a national registry for organ matching
- Called for the network to be operated by a private, not-for-profit organization under federal contract

Final Rule
- Published April 1998, amended October 1999
- Implemented March 2000
- Governs the operation of the OPTN
What is the OPTN?

- Membership organization
- Members must comply with the Final Rule and OPTN bylaws and policies
- Your OPO is a Member!

OPTN/UNOS - Introduction

The mission of the United Network for Organ Sharing (UNOS) is to advance organ availability and transplantation by uniting and supporting its communities for the benefit of patients through education, technology and policy development.

- UNOS – federal contractor that facilitates organ distribution and transplantation
- Equitable policies
- Donation awareness
- National transplant Waiting List
- Membership management
- Policy compliance
- Data collection and reporting

Get Involved – Policy Development

The OPTN policy development process relies on extensive collaboration among constituents. Members have both the right and the responsibility to participate.

Current Policy

- Visit the OPTN or UNOS website to view current policy.
How to Read the Policy

- **Underlined text** means it is not currently policy but that it will be in the future.
- A **strikeout** means the policy is still in effect, but will be going away. It’s pending either programming or notification.

---

**Patient Safety System**

- Event reported using Patient Safety System
- OPO must contact all centers involved
- UNOS Patient Safety Staff will contact the OPO, request an initial report, and give other directions needed
- OPOs will prepare a 45 day follow up report

---

**Disease Transmission Event**

- Event reported using Patient Safety System
- OPO must contact all centers involved
- UNOS Patient Safety Staff will contact the OPO, request an initial report, and give other directions needed
- OPOs will prepare a 45 day follow up report

---

**Patient Safety Applications**

- **Mandatory reporting:**
  - Disease transmission through donation
  - Malignancy
  - Infectious diseases
  - Living donor adverse events
  - Death
  - Native organ failure
- **Voluntary reporting:**
  - Any situation or activity that could have affected patient safety

**If in doubt, report it!**
Can you answer every question that a donor family member or hospital employee might ask about organ allocation?

How can you add value to your organization by learning about policy compliance?

**The Problem**
- **113,977** waiting for a transplant
  - **123** are babies under the age of 1
- About 80 lives saved today by transplant
- Approximately will 17 die today
- Around a 110 more added today

There aren’t enough.

**Allocation Policy Tenets**
- Waiting Time
- Medical Urgency
- Net Benefit
- Justice
- Utility

**Organ-Specific Policy**
Purpose: provide a high-level overview of listing/allocation policies for each organ

As an OPO coordinator, why do I need to know organ allocation policy?

**Kidney**
- Based on points system, points are assigned for:
  - Waiting time
  - Sensitization
  - Quality of antigen mis-match
  - Pediatric status
  - Prior living kidney donation
- Mandatory Shares: 0mm for sensitized candidates, paybacks
- Allocation is local, regional, national
Pancreas
- Based on: waiting time, candidate sensitization, level of antigen mis-match between donor and recipient
- Mandatory Shares: 0mm
- Allocation
  - Local, regional, national
  - Facilitated pancreas offers

Heart Medical Urgency
- Status 1A – Most Urgent Need
  - Hospitalized, Intubated, VAD (VAD patients are eligible for 30 days of 1A time), multiple or high dose inotropes, ECMO, IABP, etc.
- Status 1B – Less Urgent Need
  - Stable, Home, VAD, low-dose inotropes.
- Status 2 – All other patients

Adult Heart Allocation Status Descriptions
Status 1A
A- Mechanical Circulatory Support
B- Mechanical Circulatory Support with device related complications
C- Continuous Mechanical ventilation
D- Continuous specific high-dose inotropes and monitoring of certain pressures
E – Exception- life expectancy is equivalent to the other criteria and must be reviewed and approved by the Regional Review

Heart
Each candidate awaiting heart transplantation is assigned a status code which corresponds to how medically urgent it is that the candidate receive a transplant

Peer Review
- Regional Review Boards
- Review is done retrospectively
What if the candidate has been transplanted?

Options

- There is an appeals process with first the regional Review Board, followed by the Committee, then the MPSC...

Zonal Heart Allocation

- Common OPO Status 1A
- Zone A Status 1A
- Common OPO 1B
- Zone A Status 1B
- Common OPO Status 2
- Zone B Status 1A...

New Policy Implemented November 2010

3.7.8.1 Heart Allocation to Pediatric Candidates Less Than 2 Years of Age Willing Eligible to Accept a Donor Heart of Any Blood Type.

Heart

- Hearts can only be out of the body for a short time (6-8 hours)
- Allocation is zonal
  - Balance between distance & priority
Adult Lung Allocation

- Based on Net Benefit (≥ 12)
- Lung Allocation Score is calculated based on medical data

Lung

- Allocation is zonal
- Based on Waiting Time (<12)
  - New-Priority 1 and Priority 2 Status

LAS Score

Factors used to determine the LAS

- Lung diagnosis
- Date of birth
- New York Heart Association Class
- Assisted ventilation
- Height and weight
- Diabetes
- Supplemental oxygen
- Percent predicted FVC
- Six minute walk
- Distance
- Serum creatinine
- Pulmonary artery systolic pressure
- Mean pulmonary artery pressure
- Pulmonary capillary wedge mean

HL Listings

- Candidates who need a HR and a LU may be listed on the HR, LU, and HL list
- Policy 3.7.7-Dictates how both matches can be used for placement.
  - Can place a HR from the LU match if no suitable 1A isolated HR candidates are eligible.

Peer Review

- National Review Board
- Cases reviewed prospectively

Liver Allocation

Each candidate awaiting a liver is assigned a status code based on Medical Urgency:
Status 1A, 1B, MELD, PELD
Adult Liver Allocation Status Descriptions

- 1A: Candidate has fulminate liver failure with a life expectancy without a liver transplant of less than 7 days
  - fulminate hepatic failure defined as the onset of hepatic encephalopathy within 8 weeks of the first symptoms of liver disease

MELD/PELD Scores

All other adult liver transplant candidates on the Waiting List shall be assigned a mortality risk score calculated in accordance with the MELD/PELD scoring system.

For each liver candidate registration, the listing transplant center shall enter data on UNOS® for the prognostic factors:
  - Creatinine
  - Bilirubin
  - INR

These data must be based on the most recent clinical information (e.g., laboratory test results and diagnosis) and include the dates of the laboratory tests.

Liver Candidates with Exceptional Cases

Peer Review
- Status 1A/B: retrospective review by a subcommittee of the Liver Committee
- MELD/PELD: prospective review by the regional review boards

Liver Allocation Status Descriptions

MELD- Model for End-Stage Liver Disease
All other adult liver transplant candidates on the Waiting List shall be assigned a mortality risk score

PELD- Pediatric End-Stage Liver Disease
Pediatric liver transplant candidates less than age 12 shall be assigned a mortality risk score

Balance between Distance & Priority

Livers are allocated based on medical urgency, ABO, geographical considerations (regional) and age of the donor.
Adult donors (>18)

- Local and regional status 1A, and then local and regional 1B candidates for adults and peds are combined
- Local MELD/PELD ≥ 15 - Adult and Pediatric
- Regional LI MELD/PELD ≥ 15 - Adult and Pediatric
- Local MELD/PELD < 15 - Adult and Pediatric Age 0-17...

Liver Donors age 0-11

Local and regional 1A peds (0-17) are combined; National 1A candidates for peds 0-11 prior to local status 1A adult candidates.

Intestine

- Based on Medical Urgency: Status 1, Status 2, Status 7
- Allocation
  - Local, regional, national
  - Greater sharing of liver/intestine grafts

Bonus Question #1

- Why is there not a status 1 category for adult lung allocation?

Bonus Question #2

- Why is there not a review board for kidney allocation?
Policy Review Using Case Studies

Sample Scenario – Patient Safety
You make a heart offer for Victor Vad, and the transplant center calls to ask if they can use the heart for a more critical patient who was listed today (Carl Cardiogenic). What policies apply? What’s the reason for those policies?

- Policy 3.2.4
  - Organs shall be allocated only to candidates who appear on a match run
  - If the intended recipient is unavailable to receive the transplant, the organ shall be re-allocated according to the match run
  - If Carl Cardiogenic is more critical, why didn’t he appear above Victor Vad on the match run? Is he on the match run? If not, why?
    - Maybe a second user didn’t verify his ABO, using source documents, after he was added to the waiting list (3.1.4)
    - Maybe there is an unacceptable antigen
    - Maybe the serology status is not compatible
    - Maybe there isn’t time for a preliminary x-match

You don’t want to guess!

- The match run is an allocation tool and a basic patient safety mechanism; you don’t want to take chances. Make sure the candidate appears on the match run.
- There is a way to find out why a candidate doesn’t appear on a match run, do you know how to do that? (instructions & screenshots included as reference)

Finding a Specific Candidate on the Match Results List
To find a specific candidate on a match results list, or to find a candidate who was screened off the list, take the following steps:

1. Access a donor’s match.
2. From the match results page, click the Find icon at the upper right-hand corner. Enter a transplant center and any other search criteria. Then click the GO button.
3. Based upon the search criteria entered, search results display. To view organ offer information on the candidate’s record, click the link within the area of the candidate’s name.
4. Organ offer information displays for the candidate you selected.
Sample Scenario

You just made a regional liver offer for Harry Hepatorenal, but the transplant coordinator calls to tell you he also needs a kidney. Both kidneys have already been accepted, one is going with the heart to a heart-kidney candidate and one is going to a 0mm kidney/pancreas candidate. What policies apply?

- Scenario facts
  - Regional liver offer
  - Kidney accepted for heart-kidney candidate
  - Kidney accepted for 0mm kidney/pancreas candidate

- Policy 3.9.3
  - Required allocation when the donor is local
  - Voluntary sharing recommended when donor is not local

- Scenario facts
  - Regional liver offer
  - Kidney accepted for heart-kidney candidate
  - Kidney accepted for 0mm kidney/pancreas candidate

- Policy 3.3.6
  - Once an organ is accepted without conditions, the OPO and TXC are bound by that agreement

- Scenario facts
  - Regional liver offer
  - Kidney accepted for heart-kidney candidate
  - Kidney accepted for 0mm kidney/pancreas candidate

- Policy 3.5.4
  - If kidney/pancreas are procured with option of simultaneous KP tx and there is a 0mm KP candidate, the KP must be offered to that candidate
What if...
- it was a local donor?
- the heart-kidney program hadn’t accepted yet?
- the kidney-pancreas candidate was a kidney-lung candidate?

There are many combinations!
- Policies don’t exist in a vacuum
- You may have to read more than one policy to find your answer

When in doubt...
- Ask-call the Organ Center, regional administrator, or a representative from department of evaluation and quality (allocation analysts, review board coordinator).
- Document, document, document!

Electronic Notifications and DonorNet®
- An organ offer received electronically through voice and text messages
- A web based system that allows the sharing of information electronically
- Mobile technology flexibility
Benefits of Electronic Notifications

- Reduce organ placement time
- Receive offer refusal faster
- Focus efforts on interested TXCs
- Notify multiple TXCs of organ programs at the same time
- Reduce the risk of out of sequence allocation

Add Donor Attachments

- Add the donor (two ABO verifications)
- Enter donor information
- Attach relevant documents
- Run Matches
- Electronically notify TXC's

DonorNet*

Attachment Information

- File types: pdf, jpg, avi, pdf, xls, doc, tif, many
- Some potential harmful files not allowed, .exe
- Unique file types—be careful
- TXC may not be able to open
- Cannot upload files after 30 days of adding the donor
- Max file size is 50 mb
- Unlimited # of attachments can be added

Edit Donor Data

- Local Deceased Donor
- Edit Data
- Upload/Download Data
- Run Matches

Run Matches

- Select matches to run
- Verify Contact Numbers for each organ match

Link to what is CDC HR
Sending Electronic Notifications

Primary offer is highlighted in yellow

Successful Notification!

Notification & Evaluation Time Limits

- OPO Sends Notification
- TXC Logs On
- TXC Response
- 1 hour max Notification
- 1 hour max Evaluation
- The system automatically continues to call both primary and secondary contact, when applicable (Escalation Process)

Matching and Screening

- All donors must be added to DonorNet®
- All candidates on Waitlist™ must have certain acceptance criteria entered
- Online donor data must be accurate and complete

The waitlist information is evaluated against the donor information to produce the results of an organ match

- Candidate A: 18 year old status 1A Liver candidate
- Hepatitis B Core negative

Accept an HCV Antibody Positive donor? No
Accept a Hepatitis B Core Antibody Positive donor? No

- Liver donor: 35 years old, Hepatitis B Core positive
- Data entry error
- Match run with serology NEGATIVE
This candidate will be on the liver match

<table>
<thead>
<tr>
<th>Snop</th>
<th>Center</th>
<th>Name</th>
<th>SNS</th>
<th>Age</th>
<th>LI</th>
</tr>
</thead>
<tbody>
<tr>
<td>380</td>
<td>UNOS</td>
<td>BACTCO Candidate</td>
<td>3474</td>
<td>53</td>
<td>10</td>
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</tbody>
</table>

What are the negative implications of this situation?

Allocation Complete

The OPO:
- **Cannot** manually or electronically notify TXC
- **Can** edit all PTR records on the match
- **Can** change allocation status back to in-progress
- Transplant center **cannot** edit response while complete.

Matching Criteria Examples

<table>
<thead>
<tr>
<th>Matching Criteria</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Status</td>
<td>Accept</td>
</tr>
<tr>
<td>Age</td>
<td>Eligible</td>
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<tr>
<td>Race</td>
<td>Eligible</td>
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<td>Gender</td>
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<tr>
<td>Blood type</td>
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<tr>
<td>HLA compatibility</td>
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<tr>
<td>Prior transplants</td>
<td>Eligible</td>
</tr>
<tr>
<td>Liver disease</td>
<td>Eligible</td>
</tr>
<tr>
<td>Prior transplantation</td>
<td>Eligible</td>
</tr>
</tbody>
</table>

Closing a Match

- The match should not be closed until the organ has been officially accepted
- The match will be considered complete only if the statuses above the acceptance are one of the following
  - Refusal, Bypass, or Accept
    Match should reflect placement not transplantation!

Completing the Allocation

- Allocation process is complete when the organ has been placed
- Different from closing a match

0mm Allocation

- 0mm- Mandatory Share
  - Must offer 5 for ECD & 10 for SCD
  - Sharing a 0mm incurs a payback (PB) credit
  - Electing to offer beyond the 5/10, if placed, will not incur the credit
  - The OPO for the importing 0mm TXC incurs a PB debit
0mm Allocation Common Questions

- OPO Question: I want to keep 1 kidney for a KP, and we are doing a HR/KI, but there are 0mm's, can we do that?
- Answer: No, according to OPTN policy, you are required to offer out 1 kidney as primary to the 0mm's, unless the KP is a 0mm or a “highly” sensitized (>80% PRA) candidate.
- 3.5.3.4 Kidney/Non-Renal Exception: When kidneys are procured for the purpose of simultaneous kidney and nonrenal organ transplantation, only one of the kidneys procured must be shared as a zero antigen mismatch. In the event the kidney/non-renal organ transplant is not performed, the kidney retained for that transplant must be immediately offered for zero antigen mismatched candidates. This exception does not apply to kidney-pancreas combined transplants or kidney-pancreas combined transplants for zero antigen mismatched highly sensitized candidates as defined in Policy 3.5.4 (Sharing of Zero Antigen Mismatched Kidneys to Combined Kidney-Pancreas Candidates).

Payback Allocations

- Payback Debts
  - Mandatory Share
  - Incurred when a 0mm, KI/Extra Renal are brought in by a TXC.
  - The debt is given to the importing OPO for that TXC.
  - Multiple Debts for an OPO create “Paybacks Owed” for the OPO.
  - Six call withdraw (committee decision)

Payback Allocation Continued

- Exemptions for offering Paybacks include the following donors:
  - ECD
  - DCD
  - Donor less than 6 years of age
  - Donor greater than 59 years of age

May still offer these donors for Payback

Payback Questions

- OPO Question: We owe 6 Paybacks, but we want to do a KP, and a LU/KI, can we do that?
- Answer: No, since the OPO owes 6 paybacks, unless the KP is a 0mm KP or a "highly" sensitized KP, they (OPO) must offer out the kidney for at least 6 days before they can do a local KP.
- 3.5.5.1 Deferment of the Kidney/Non-Renal Exception: OPOs that have accumulated six or more payback obligations within the blood type of a locally procured donor shall not be permitted to defer the obligation to offer the kidneys from this donor in satisfaction of payback debts by retaining a kidney for transplant with a non-renal organ locally, except for kidneys allocated for a kidney-pancreas transplant pursuant to Policy 3.5.4, or a kidney/non-renal organ transplant where the non-renal organ is a heart, lung, or liver. The kidney/non-renal exception shall be deferred until the OPO has reduced its payback obligation to less than six.

Payback Questions Continued

- OPO Question: We owe 6 paybacks, but we want to do a HR/KI and a LU/KI, do I have to offer out one kidney for payback.
- Answer: No, OPTN Policy will allow the OPO to offer a HR/KI and a LU/KI (both life saving organs) prior to offering a kidney for payback.
- 3.5.5.1.1 Deferment of the Kidney/Non-Renal Exception: OPOs that have accumulated six or more payback obligations within the blood type of a locally procured donor shall not be permitted to defer the obligation to offer the kidneys from this donor in satisfaction of payback debts by retaining a kidney for transplant with a non-renal organ locally, except for kidneys allocated for a kidney-pancreas transplant pursuant to Policy 3.5.4, or a kidney/non-renal organ transplant where the non-renal organ is a heart, lung, or liver. The kidney/non-renal exception shall be deferred until the OPO has reduced its payback obligation to less than six.

Heart/Lung Allocation

Can we place a HR from the LU match?

- 3.7.7 Allocation of Thoracic Organs to Heart-Lung Candidates. When the candidate is eligible to receive a heart in accordance with Policy 3.7, or an approved variance to this policy, the lung shall be allocated to the heart-lung candidate from the same donor. When the candidate is eligible to receive a lung in accordance with Policy 3.7, or an approved variance to this policy, the heart shall be allocated to the heart-lung candidate from the same donor if no suitable Status 1A isolated heart candidates are eligible to receive the heart.
Heart/Lung Allocation Continued

What does this mean?
- It means the HR can be allocated to a HL recipient on the LJ match if no status 1A hearts are within the same classification as the HL candidate on the LJ list.
- The same classification would mean within the OPO or Zone A or Zone B, etc.
- The OPO does not need to offer to all status 1A candidates through Zone D before placing a HR from the LJ match. They only need to offer to all 1A HR candidates on the HL match through the classification from which they want to place the HR from the LJ match.

Additional OPO Responsibilities

Providing required documentation to agencies

Additional documentation may be requested by:
- Tissue agencies
- Medical examiners
- OPTN

Screening for and reporting about transmissible diseases:
- Policies: 4.1, 4.1.1, 4.6, 4.7

Travel arrangements

- Host OPO is responsible for ensuring all non-local recovery teams have transportation to and from the local airport.
- Host OPO is responsible for transportation of deceased donor kidneys and tissue typing material to the primary destination.
- Transportation cost allocation is described in policies 5.6.2 and 5.6.3.

Providing required documentation to agencies

- Documentation of authorization
- ABO typing X 2
- Serology results
- Medical Social History
- Donor evaluation/maintenance/interventions (chart)
- Documentation of organ quality

This documentation must accompany an organ!

Vessels

- 5.4.3 Vessels if packaged separately from the organ:
  - The vessels must be protected by a triple sterile barrier, one of which must be a rigid container.
  - Labeled with: recovery date,
  - ABO,
  - All serology results,
  - Container contents,
  - And the UNOS donor ID.
  - If the donor is in a "high risk" group as defined by the Centers for Disease Control and Prevention (CDC), the label must indicate that the vessels are from a donor who meets the CDC criteria for high risk.
Organ Center Assistance

- Organ Center required to make the following offers;
  - Paybacks
  - National KI, KP, PA (PI not included)
  - Only OC can make facilitated PA offers
    - What is a facilitated PA offer?
  - 0mm offers can be made by OPO, must submit acceptance documentation w/in 5 business days.

Organ Center’s Role

Organ Transportation (10+ per day)

What is a facilitated PA offer?

- 0mm offers can be made by OPO, must submit acceptance documentation w/in 5 business days.

Resources

What one thing will you do today that you’ve learned?

www.optn.org

Websites

- [https://portal.unos.org](https://portal.unos.org) (Secure Enterprise)
- [http://optn.transplant.hrsa.gov](http://optn.transplant.hrsa.gov)
- [http://www.unos.org](http://www.unos.org)

Contacts

- UNOS helpdesk @ 800.978.4334 or unethelpdesk@unos.org
- UNOS Organ Center @ 800.292.9537
- evaluationandquality@unos.org
WELCOME

Physical Assessment and Donor Suitability

AOPO Standards

- CL.4B.0 The evaluation of the donor shall include:
  - CL.4B.1 An inquiry designed to gain insight into the donor’s medical, behavioral, and sexual history shall be conducted with the potential donor’s next of kin, significant life partner and/or other appropriate individuals utilizing a standardized history questionnaire.
  - CL.4B.2 Documented physical examination
  - CL.4B.3 Documentation of ABO group (and subgroup, if applicable), weight and height
  - CL.4B.4 Review of current inpatient medical record
  - CL.4B.5 Documentation of significant events in the clinical course. The current hospital history shall include:
    - CL.4B.5.1 description of injuries and treatments (i.e., surgeries).

Notice / Warning

- This presentation includes graphic photos of physical assessment findings which may be indicators of increased risk for HIV, hepatitis or other infectious diseases.
- It is intended for tissue / organ recovery professionals and viewer discretion is advised.

Training Objectives

Participant is able to define or describe:

- 1. relevant policies, regulations & standards
- 2. usefulness of all donor medical records
- 3. STD, HIV, Hepatitis, and Cancer prevalence in the US
- 4. physical signs associated with risk for HIV & Hepatitis
- 5. physical signs associated with other systemic processes
- 6. vaccination site assessment related to Smallpox vaccine
- 7. reasons for declining recovery of specific types of tissue

Federal Regulations for Tissue

  - AATB adopted these federal regulations; first appeared in the 1998 edition of AATB Standards
  - Suggests the need to document if an autopsy is planned or not
  - To ensure that all listed items are covered, Tissue Banks do not solely rely on exams/autopsy done by ‘others’

Federal Regulations for Tissue

1271.50, 75, 80, 85 Requirements

- 1271.190 Facilities
- 1271.195 Environmental Controls
- 1271.190 Equipment
- 1271.190 Supplies & Reagents
- 1271.200 Storage
- 1271.200 Processing Controls
- 1271.200 Recover Controls
- 1271.190 Labeling Controls
- 1271.200 Receipt, Pre-Dist. Shipping & Distribution
- 1271.200 Other Tissues & Specimens
Federal Regulations for Tissue


Physical assessment is defined as “a limited autopsy or recent antemortem or postmortem physical examination of the donor to assess for any signs of HIV and Hepatitis infection or signs suggestive of any risk factor for such infections.”

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AATB Added Requirements

**12th Edition Standards of Tissue Banking**

- Sepsis, such as unexplained general rash/petechiae or fever;
- Large scab consistent with recent smallpox vaccine
- Eczema Vaccinatum
- Generalized vesicular rash
- Necrotic skin lesions consistent w/Vaccinia necrosum
- Corneal scarring consistent w/vaccinial keratitis

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Federal Regulations for Tissue


“Relevant medical records means a collection of documents including a donor medical history interview, a physical assessment of the donor, laboratory test results, medical records, existing coroner and autopsy reports, or information obtained from any source or records which may pertain to donor suitability regarding high risk behaviors, clinical signs and symptoms for HIV and Hepatitis, and treatments related to medical conditions suggestive of such risk.”

---

AATB Standards

**Standards**

- **Section D - Acquisition of Tissue: Consent, Donor Screening, Tissue Retrieval**
  - D4.000 Donor Suitability; D4.200 Assessment; D4.210 Physical Assessment:
    - Performed prior to retrieval, done by a responsible person (authorized, trained & qualified)
    - Assess for evidence of high risk behavior, HIV infection, hepatitis infection, bacterial or viral infection, or trauma to retrieval sites
    - Observed at assessment or noted in any other available record
    - Indicates review of records is related to physical assessment

---

Federal Regulations for Tissue

- The following findings should be reported when performing an ante mortem or post mortem physical examination...
  - STDs such as GUDs, herpes simplex, syphilis, chancroid
  - Disseminated lymphadenopathy
  - Oral Thrush
  - Blue or purple spots consistent with Kaposi’s Sarcoma
  - Anal intercourse including perianal condyloma
  - Non-medical percutaneous drug use such as needle tracks
  - Needle tracks, including examination of tattoos which may be covering needle tracks
  - Unexplained jaundice, hepatomegaly, or icterus

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AATB Standards

**Standards**

- **D4.220 Donor Risk Assessment**
  - Medical, Social and Sexual History Inquiry
    - Questions formulated using the USPHS Guidelines for Preventing Transmission of HIV Through Transplantation of Human Tissues and Organs also:
      - Diagnosis or treatment for STDs in the past year?
      - Sexual warts, herpes
      - Been seen by a physician in the past 2 years?
      - Disease history that could affect external observations
      - Recent flu-like symptoms
      - Sore throat, active viral infection, rash
      - Cancer history?
      - Skin, treatment types, weight loss/emaciated
      - Surgical history?
      - Recent smallpox or live vaccine
Standards

- D4.230 Relevant Medical Records Review
  - Prior to retrieval a preliminary review of readily available medical information shall be conducted by a trained individual.
  - Includes previous and current medical records, test results, conversations with attendant medical staff and/or family members.

This information can explain findings during the physical assessment and it must be reviewed before tissue retrieval begins.

Preparation for Physical Assessment

- Match age, race, sex, height, and weight with information available in records
- If there is a discrepancy, it must be resolved and documented
- It’s important to weight the body if there is an obvious weight discrepancy as hemodilution assessment may be compromised
- The information you report is reviewed by many, including Medical Directors in determining suitability of tissue for release.

Tissue Donor Physical Assessment Form

- Undress the donor, but be careful removing clothing
  - Beware of illegal drugs and drug paraphernalia (sharps)
- Note bullets, pellets, blades and save them in labeled container(s)
- Contact your administrator on call for directions; consult hospital supervisor, law enforcement, Medical Examiner
- Place all clothing in a labeled bag
- Document all personal items bagged or remaining on body (rings, watch, jewelry) or absence thereof
- Some recovery agencies use a separate form to track ‘custody’ of articles

Preparing for the Physical Assessment

- Secure the area
  - Cover windows
  - Are “observers” allowed?
  - Best to write a policy and train staff regarding these situations
- Adequate lighting
  - If morgue lighting insufficient, wait until in the OR
- Appropriately identify the body
  - Match name on consent (authorization) form with body ID
  - If body is not tagged, what is an acceptable method of ID?
  - This scenario requires proper, thorough documentation; admin. on call consult?

Photography (optional)
- May take both pre & post photos; document actions in the record; photos should be available to processor, if requested
- In photos, use identifier placard; lay ruler next to finding
- Consider photographing the means of identification
Preparing for the Physical Assessment

- Review available, relevant medical records
  - Consent (Authorization) document
  - Medical history & behavioral risk assessment questionnaire
  - All relevant donor screening documentation (team should have this)
  - May contain M.E. / Hospital Pathologist/Funeral Home requests or extra information rec’d & documented by personnel obtaining consent, med/soc hx, or communications while arranging recovery site

Preventing the Physical Assessment

- Review available, relevant medical records
  - If applicable:
    - Infusion/transfusion documentation (invasive lines placed where?)
    - EMS run sheets
    - ER flow sheets
    - Available hospital chart (records)
      - History & Physical, Progess Notes, laboratory results, CXR, culture results, scans, any medical intervention (surgery, therapy)
    - Morgue sign-in, sign-out records (Are refrigeration times consistent?)

Top 10 Things to Remember...cont’d

5. Always remove all articles of clothing
4. Always turn the body over
3. Inspect all orifices
2. Look above, below and between
1. Approach the exam systematically

Top 10 Things to Remember When Performing a Physical Assessment

10. Verify reported information, don’t “assume” as fact
9. Never take shortcuts
8. Don’t assume a finding means nothing
7. If you don’t know what it is, don’t guess
6. Never hesitate to ask for help

Physical Assessment Methods

- Follow a systematic approach that covers all areas
  - Start anteriorly (supine) at the head and examine down to the feet (or vice versa)
  - Turn the donor posteriorly (prone) and again examine from the head down to the feet (or vice versa)
  - Examine genital area and buttocks (both sexes) This is required for every donor, all ages

If you don’t look posteriorly, you could miss a melanoma, perianal condyloma, or decubitus ulcer, all of which affect donor suitability.

AATB Documentation

- At physical assessment, it would be incorrect to use wording such as ‘herpes’, ‘syphilis’, ‘chancroid’, ‘thrush’, and ‘Kaposi’s sarcoma’, since diagnostic testing would be required to make these ‘diagnoses’
  - Use “genital lesions”, “white spots in mouth”, and “blue/purple (gray/black) spots/lesions” since these are actual observations that can be documented.
  - Use “insertion trauma, perianal warty”, instead of “anal intercourse, perianal condyloma”
  - Use “enlarged lymph nodes” instead of “disseminated lymphadenopathy”
AATB Documentation

- Use “non-medical injection sites” instead of “physical evidence of non-medical percutaneous drug use such as “needle tracks”, and “needle tracks, including examination of tattoos which may be covering needle tracks”
- Use “jaundice/icterus” instead of “unexplained jaundice, hepatomegaly, or icterus”

Health Care in U.S.A.

- “Nearly One in Five Americans Say They Can’t Afford Needed Health Care”
  For Immediate Release
  Monday, December 3, 2007
  Contact: CDC National Center for Health Statistics Press Office (301) 458-4800
  E-mail: panquery@cdc.gov

AATB Documentation

- Write “unremarkable” if nothing noted on a total body view (e.g. the posterior view). Do not leave entire view blank!
- If fluids/transfusions were given or documented, there should be a puncture site on the schematic that correlates with that event

Population Growth

source: Health United States 2007

Assumptions and Facts

Many potential donors do not receive routine medical care, so visible physical abnormalities may be observed during donor assessment which have not been previously ‘diagnosed’.

The reliability of sexual behavior risk answers on the questionnaire is dependant upon the historian’s knowledge.

a) Unless the historian is the sole sexual partner of the donor, which can never be known with certainty, the reliability of the answers by the historian to sexual behavior risk questions is limited.

b) Knowledge of current and past drug use, too, may be limited.

Assumptions and Facts

The quality of the physical assessment of the donor rests with the staff performing it and the training they’ve received. Potential indicators for high risk behavior will be missed if the genital exam is not performed properly.

- Anal intercourse is a known, risky sexual behavior for either sex. - per the Surgeon General of the USA
- Don’t just ‘peek’, inspect......

Expect to find the unexpected!
These 4 sources of information must be consistent. If not, the inconsistency must be resolved. Background education & experience enhances the on-the-job training.

**New Gonorrhea cases per 100,000 population:** 125.0

**Number of new Gonorrhea cases:** 351,852 (2002)

**New Chlamydia cases per 100,000 population:** 296.6

**Number of new Chlamydia cases:** 834,555 (2002)

**New syphilis cases per 100,000 population:** 11.7

**Number of new Syphilis cases:** 32,871 (2002)

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**Sexually Transmitted Diseases**

- **Morbidity**
  - Number of new Syphilis cases: 32,871 (2002)
  - New syphilis cases per 100,000 population: 11.7 (2002)
  - Number of new Chlamydia cases: 834,555 (2002)
  - New Chlamydia cases per 100,000 population: 296.6 (2002)
  - Number of new Gonorrhea cases: 351,852 (2002)
  - New Gonorrhea cases per 100,000 population: 125.0 (2002)

- Source: *Health United States: 2004, table 51*

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**Acute HIV Illness**

*Primary HIV* = the period from initial infection to complete seroconversion, a period of extreme infectiousness. May be symptomatic or asymptomatic.

- **Fever** (mean temp 39.4° C [102.9°F]); > 80%
- **Rash**, lymphadenopathy, arthralgia or myalgia, sore throat, fatigue, H/A; 40-80%
- Oral ulcers and/or genital ulcers, > 5Kg weight loss, nausea, vomiting, diarrhea; 10-40%

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**Hepatitis & HIV**

CDC & NCI estimates:

- **HAV** = 13% of Americans have evidence of past infection; Historic; 3% in 1990’s following immunization
- **HIV** = 1.2 million (30% acquired in childhood) Americans affected; 60,000 new infection in 2004 (down from 260,000 in 1983)
- **HCV** = 4.1 million Americans infected; 19,000 new infection in 2006 (down from 240K in 1988)
- **AIDS** = end of 2003 a total of 1.09M-1.185 M cases; (24 - 37% unaware)
  - 3 times as many are HIV Ab pos (> 1 million)
  - 24%; 27% of these folks may be unaware of their HIV+ status (2003)
  - 33% who know HIV+ status may not be receiving medical care
  - 38,828 AIDS cases were diagnosed in 2006 (2002 had 38,112 cases)

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**Exanthem**

Maculopapular rash = skin ‘spots’, ‘raised’, ‘eruptions’

Etiology: Must be known in order to be able to assess donor suitability.
**Why is it an issue?**

HIV subculture: “Safer sex is not real sex, it’s pretend sex”.
- **Barebacking** = intentional anal sex without a condom w/someone other than primary partner.
- **Bug chasers** = HIV negative individuals seeking to become infected from HIV + “gift-givers”.
- Through HAART, HIV has become viewed as a ‘manageable’ disease.

**Genital Ulcerative Diseases**

- In the U.S., most individuals with genital ulcers have either herpes, syphilis, or chancroid
- 3%-10% have more than one disease
- Syphilis and Gonorrhea are associated with an increased risk for HIV infection (due to an epidemiological synergy; heterosexual population)
- An active GUD offers an open route for transmission of viral and bacterial diseases from person to person

**Infectious Disease Testing**

The ‘window periods’...
(The time from exposure to testing positive)
- HBV = 5-7 weeks
- HCV = 70 days (NAT = 20 days)
- Syphilis testing = 3 months
- HIV from 11 days to weeks to months; depends on the type of testing performed as well as viral load at exposure

**Primary Syphilis**

- Red, “meaty colored” chancre that is usually round or oval
- Males: penis on the inner prepuce, coronal sulcus of the glans penis
- Females: cervix, vagina, vulva, clitoris, and breast
- Also found on anus or rectum, tongue, and lips, dependant on sexual behaviors

**STD Prevalence in the USA**

- Estimation of population (= 291 million) in USA with:
  - Syphilis = 32,871 cases (all stages) in 2002 (reported)
  - Gonorrhea = 351,852 new cases in ’02 (it is expected that there are an equal number of unreported cases)
  - Chlamydia = 834,555 new cases in ’02
  - Human Papillomavirus (HPV, genital warts) = 1 to 5 million new cases annually + 20 million Americans affected; > 1% sexually active adults have visible warts
  - Genital herpes = 500,000 to 1 million new cases annually + 60 million Americans affected; 1 in 5 people over the age of 12 may be infected
Herpes Simplex Virus Type 2

“Genital Herpes”
- Lesions may appear on the penis, scrotum, thighs or buttocks on a male, and labia, inner thighs and buttocks of a female.
- The most significant factor is that since this is an active GUD, it offers an open route for the potential for recent disease transmission. Could infectious disease testing be negative but they are currently infectious?

Human Papilloma Virus (HPV)

Genital Herpes

HPV - Genital

Non-medical Injection Sites

- Injection of drugs may create “tracks” over accessible veins with scarring at old injection sites.
- Today, due to high purity of drugs, these may be harder to visualize since localized skin reactions are reduced.

Any tissue donor with suspected non-medical acute injection sites is ruled-out; Any history ever of IVDA is ruled-out by some processors (AATB standards 5 ytrs.)

Human Papillomavirus (HPV)

- Pinhead papules to cauliflower-like masses
- Skin-colored, pink, or red
- Soft and usually found in clusters
- This is not classified as a GUD but is a genital lesion that may be a significant finding
  - Location can be critical, and incidence of cancer is increased (cervical, anogenital) if untreated
  - Presence vs. Questionnaire’s ‘no’ answer to STDS (?)

If perianal warts are found on a female donor is this a rule-out for tissue donation? Medical Director discretion. What’s your written policy?
Non-medical Injection Sites

Can be palpable due to scarring of tissue

Old healed site

Medical Injection vs. Non-medical sites

Is this jaundice? Yes or No

Icterus / Jaundice

Icterus/Jaundice found in sclera may be the sole finding if subject is dark-skinned

Note: < 20% of those with acute HCV present with jaundice.
**Disseminated Lymphadenopathy**

‘sclurred lymph nodes’

Common Sites
- Neck (under the jaw line)
- Axillary (armpit)
- Inguinal (groin)

May be the size of a pea to a golf ball

Document location and size of swollen nodes

- Unusual node(s) could be biopsied
- Acceptable reasons may be: recent sore throat (neck); PVD/drainage compromised (inguinal)

Unacceptable reasons could include a systemic disease

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**Oral Thrush**

**‘white spots in the mouth’**

- White to creamy plaques or curds that can be removed with dry gauze
- Thrush can be found in the mouth, vagina, and under the breasts
- Present with HIV, an immunocompromised state, or may simply be a reaction to current antibiotic therapy

- If findings are present, this would require determination of etiology for tissue donation. Not an automatic deferral.

---

**Swollen Lymph Nodes**

**Kaposi’s Sarcoma**

**Blue or Purple Spots**

- Present with HIV or an immunocompromised state (e.g. organ transplant recipients); usually appears with lymphadenopathy
- Found mostly on trunk, legs, nose, and mouth but can be found anywhere (early stages may begin between toes)
- Either oval or oblong lesions that are palpable
  - If not palpable, it may only be a bruise
- May appear as a gray or black color on a body post mortem
- Occurrence much more predominant in males vs. females (15:1)

---

**Oral Thrush**

**Kaposi’s Sarcoma**

Clusters on groin/anterior thigh

Note raised areas called papules, plaques (which are not seen in birthmarks)

Color also different than that found with birthmarks
Kaposi’s Sarcoma

Tattoos

- ‘Jail-made’ tattoo
- Single color (black)
- Not ‘professional’ but well executed
- Syphilitic rash also present

Kaposi Sarcoma

Tattoos

- ‘New Tattoo’
  An older tattoo would not be this vibrant.
  Recent enhancement of a tattoo is treated as a new tattoo.

Tattoos

- Color
  - Black - May be suggestive of “jailhouse” tattoo
  - Bluish - Usually homemade
  - Multicolored - “Professional” (Does not ensure safety)
  - Recent enhancements are considered as “new” tattoo
- Placement
  - Over arms and legs to possibly conceal IV drug injection sites
- Subject
  - Often relevant to lifestyle. Does it suggest “risky behavior”? 

Any suspicion of shared needles/instruments in the past 12 months is a rule-out per federal regulations

Tattoos

- New tattoo outline on a back just 13 hrs post application
- Scabbing of a 3 day old tattoo.
  Note shaved area
Tattoos & IVDA

Note reddened injection site within eye of tattoo

Tattoos

Teardrop “tat”:
Reportedly represents that a loved one has
died during their incarceration.
Can also mean that a
murder has been
committed by them.

Also seen in
“Wannabes”

Gang Tattoos

Prison Associated Gangs
– Mexican Mafia
– Aryan
Brotherhood
– Black Guerrilla
Family
– Nuestra Family
– Texas Syndicate

Other Tattoos

Satanic Group

“La Vida Loca”

Gang Tattoos

KKK
Aryan Nations
AWB
Skinheads
Peckerwoods
Neo-Nazis

Strongly associated with high-risk activities

Gangs & ‘Risk’

Potential infectious disease risk
– Drug abuse and sales (hard drugs, IVDA)
– Sexual promiscuity (multiple partners, unprotected
sex)
– Incarceration (long-term)
– Tattoos (needle-sharing, ink ‘reservoirs’)
– Knowledgeable historian? Most recent hx?
“Window period” concerns….
Incarceration & ‘Risk’

Correctional System statistics
- 0.7% of U.S. population; > 2 million
- In 2000, more than 8 million were released from prison
- Disproportionately higher rates of infectious disease
  - 12-39% of all Americans w/chronic HBV or HCV
  - 4% of all Americans w/AIDS
- 2-30% of inmates have sex while incarcerated
- Upon release, inmates may resume high risk behaviors

UV Light Visible Tattoos

Evidence of Anal Intercourse

Per-act Relative Risk (%) for HIV Infection

<table>
<thead>
<tr>
<th>Sex Act</th>
<th>Relative Risk (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insertive fellatio</td>
<td>1</td>
</tr>
<tr>
<td>Receptive fellatio</td>
<td>2</td>
</tr>
<tr>
<td>Insertive vaginal sex</td>
<td>10</td>
</tr>
<tr>
<td>Receptive vaginal sex</td>
<td>20</td>
</tr>
<tr>
<td>Insertive anal sex</td>
<td>13</td>
</tr>
<tr>
<td>Receptive anal sex</td>
<td>100</td>
</tr>
</tbody>
</table>

Condom Use
- Yes 1
- No 20

MMWR Recommendations & Reports; January 24, 2003 /52 (RR01); 1-33; Prevention and Control of Infections with Hepatitis Viruses in Correctional Settings

MMWR Recommendations & Reports July 18, 2003 /52 (RR12); 1-24; Incorporating HIV Prevention into the Medical Care of Persons Living with HIV

Documentation of a tattoo includes the apparent age, subject matter, location.
Mucosal Tearing

The anal canal’s mucosal lining is highly absorbent

Other Considerations

- Physical signs associated with other systemic processes (cancer, autoimmune disease, other ‘viral’ diseases and vaccinations)

Body Piercing

Ear piercing
- Acceptable if done under controlled conditions; not considered same risk as body piercing

Body piercing
- Location of piercing must be documented
- Is there documentation regarding where it was done & when? If not...what action is required?
- Also, any suspicion of shared instruments/needles in the past 12 months is a rule-out per federal regulations for tissue

Body Piercing

Body piercing

Cancer Incidence USA

Melanoma

Develops most often on sun-exposed skin; lesions generally contain no hair; may originate as a mole; changes may include:
1. Asymmetry of the mole,
2. A mottled appearance (variations in appearance from shades of brown to bluish tints),
3. Irregular or notched borders, and
4. Oozing or bleeding, or
5. A change in texture

Other Considerations

- Physical signs associated with other systemic processes (cancer, autoimmune disease, other ‘viral’ diseases and vaccinations)
Biopsy Kit

Squamous Cell Carcinoma

Lobulated or necrotic
Hyperpigmented

Basal Cell Carcinoma

Lymphoma Cutis

Recurrent Basal Cell Carcinoma

Small Pox Vaccination

Primary Vaccination Site Reaction

Day 4
Day 7
Day 14
Day 21
Recent Smallpox Vaccination

- 3 week deferral from date of vaccination
- If complications are reported, defer until 2 weeks after complications are resolved
- Check for and document that scab at inoculation site is healed
- If it is known that the scab was removed prior to separating spontaneously, defer for 8 weeks from date of vaccination

Smallpox Immunization Site

Vaccination Scar

Smallpox vaccine Adverse Side Effects

Eczema Vaccinatum
Vaccinal Keratitis

Scleroderma (digital infarcts)

Arthritis

This diagram of the hand (copied from Gray's Anatomy) shows the joints most likely affected by Rheumatoid arthritis (in blue) and Osteoarthritis or Degenerative Joint Disease (in red)

Autoimmune Disease
Discoid Lupus Erythematosus

Lesions may appear darker, post mortem
Rheumatoid Arthritis

Severe
Note: ulnar deviation of fingers

Skin Ulcers

Acceptable- Localized condition only

Unacceptable- Systemic involvement (e.g. lymph node enlargement, fever, elevated WBC w/ left shift)

Herpes Zoster (Shingles)

If acceptable, defer only tissues adjacent to the ulcer

Skin Ulcer

Specific Conditions

Stages of Decubitus Ulcer
**MS Recovery in Presence of Trauma**

- Determine extent of trauma
  - Type of fracture, abrasions, burns, location
  - Can these areas be successfully isolated?
- Assess wound condition
  - Contaminated with debri vs ‘clean’
- Decision-making
  - Do team members present possess skills required to properly isolate trauma and recover unaffected areas? Reconstruct?
  - Recover all tissues? Don’t recover some tissues? Don’t recover any tissues? ... communicate with processor
- Develop & follow SOPs
  - Document if any deviation from usual procedures

**Unusual Finding**

- Do not guess! Your concern is our concern
- Document it – photograph if possible
- Describe scenario as completely as possible
- As needed, consult physician if one is available
- As needed, consult your Administrator on call, Medical Examiner, or hospital pathologist

“Consult unresolved questions”

**“Dementia”**

- Always be alert for any mention of DEMENTIA in any chart or medical record. Any Neurologic/psychologic findings?
- Unexplained dementia is a risk factor for Creutzfeldt-Jakob Disease (CJD) or vCJD, the “human form of Mad Cow Disease”. These diseases are transmissible through transplantation and are incurable.

**MS/Trauma - Sample Policy**

*Closed Fracture with Lacerations*

Isolate traumatized areas and prep last; isolate when draping; assess suitability of individual injured areas; sequence recovery of “suitable” traumatized areas after unaffected tissues have been recovered. Open fractures and associated tissues (e.g. tendons) are not recovered.

**MS/Trauma Sample Policy**

*Contused & Abraded Areas*

Prep these areas last; isolate when draping; Recover tissues from these areas last

**Common Abnormalities**

*Common Abnormalities*

(MS and HV samples)
Common skin lesion ("Athletes Foot")

Tinea Pedis

Advance putrefaction / decomposition

(Skin slippage)
Possibly due to ambient heat, drug related, temperature or post-mortem interval

Hygiene

Scabies

Heart for Valves

Pulmonary Embolism:
At recovery, you may note clots in one or both pulmonary arteries & deep leg veins. If autopsied, place clots in a labeled container for Pathologist. Best if fixed in formalin.

Note: Send clots to ME labeled, "contents of deep veins/arteries of leg"

Caused of death was a PE

Abnormal Pericardial Findings

Cardiac Tamponade

Hemopericardium

Hidradenitis Suppurativa
(Left Inguinal area)
Bacterial Pancarditis

Heart Abnormalities

Heart Abnormalities

Awareness & Thank You

- Donors and their families have made us ‘stewards’ of their Gift, and recipients rely on us to provide safe tissues for their transplant.
- Thank you for your commitment, diligence, attention to detail, and the professionalism you practice when performing donor suitability assessments and tissue recoveries.

“It’s a very important piece in the success of transplantation”.

Questions?
Why Hospital Development?

In 1990s it was recognized that:
- 5-10% of deaths are potential O/T/E donors
- 25-50% actually become donors
- Reasons for low recovery:
  - Identification
  - Referral
  - Consent / Decline

History – In 1998 (cont.)

- These conditions include:
  1) Requiring hospitals to report all deaths to the local OPO
  2) Ensuring that the NOK be given appropriate options to donate when criteria met
  3) The donation approach must be an OPO coordinator or a person trained by the OPO as a “designated requestor”

History – In 1998

- VP Gore & HHS Secretary Donna Shalala announced National Organ and Tissue Donation Initiative to improve recovery rates
- Goal:
  - Increase organ donors by 20% over 2 yrs
- Health Care Finance Administration (HCFA) Hospital Conditions of Participation
  - Required hospitals to comply with efforts to increase donation rates

Objectives

- Who are donation champions?
- How do you establish and analyze hospital performance goals?
- How do you establish and measure clinical triggers for timely referrals of all potential donors?

- What formal processes and reports does the OPO generate and communicate to the hospital?
- How does one build a strong culture of accountability and maintain strong, professional, and collaborative relationships?
- What is the procurement transplant professionals role in hospital services / development?
• A systematic and proactive approach and plan to facilitate and maximize both organ and tissue donation
• The implementation of an optimal system to deliver high quality process every time
• A marketing process
• Delicate and deliberate relationship building for improved collaboration

Semantics?
• Hospital Development Coordinator
• Donation Consultant
• Hospital Liaison
• Hospital Specialist
• Professional Relations Coordinator
• Hospital Services Coordinator

• Trauma vs Non-Trauma
• Academic vs Non-Academic
• Urban vs Suburban vs Rural
• Receptive vs Compliant
• Collaborative vs Combative

• Where we started to where we are
  - Collaboration and relationships
  - National Associations on Board
  - Partnership for Organ Donation
  - OPO Education, Hospital Education and Rounds
  - Hospital Education and Rounds
  - Waiting for Donors

• Relationships
• Legislation and regulatory guidance
• Policies and procedure consultation
• Implementing / Refining the donation process
• Reports and data provision
• Valuable partnerships

• Hospital-Based OPO
• Free Standing OPO
• Organ Only OPO
• Organ and Tissue OPO
• Dedicated HD Staff
• Team Oriented HD Efforts
• Clinically Driven HD Efforts
Relationships

- Key Administrative Personnel
- Physicians
- Clinical Staff
- Chaplains and Social Workers
- Educators
- Quality and Performance Improvement

**GOAL**

- Identify Champions
- Valuable Consultant Recognition

• Involvement:
  - Build ownership
  - Build participation
  - Build balanced partnership

• Mentor:
  - Unconscious competence
  - Edifying
  - Praise

- Visibility
- Nurture:
  - Routine check-in; “how can I help?”
  - Phone / face to face; after each donor keeps it real
  - Routine updates on data
  - Anticipate needs

• Updates:
  - New policies
  - Something coming down the pike
  - Keep involved in the process

“An ardent defender or supporter of a cause or another person” (Answer.com)

• Visibility
• Nurture:
  - Spend initial time relationship building
  - Education with follow-up
• Updates:
  - Outcomes – variances
  - Attract attention

Legislative & Regulatory Guidance
• Accrediting bodies e.g. Joint Commission, American Osteopathic Association, and Det Norske Veritas (DNV)
• Federal
  – Uniform Anatomical Gift Act
  – Conditions of Participation
• State
  – Health and Safety Codes
  – Coroner Laws
  – Dept. of Public Health
• FDA (for tissue)

Implementing & Refining the Donation Process

Policy & Procedure Consultation

Policy & Procedure Consultation
• Organ, Tissue, Eye Donation policy
• DCD policy
• Administrative Consent policy
• Brain Death Declaration policy
• Cardiac Death Pronouncement policy
• Withdrawal of Care / Life-Sustaining Treatment policy
• Diligent Search policy

• Implementing / Refining the donation process

• Rounding
• Referral – HS presence
• Donors – HS presence

Advantages
• Early Intervention
• Promote Collaboration
• Evaluation
• Beginning of after action review
Demonstrating Professionalism

Suited or Armored
Positive vs Negative Message
Good-Bad-Good
High Road or Hard Road
Stay Out of Dodge

• Who are “Key Hospital Staff”?
• Determine attitudes and knowledge regarding donation
• Collect qualitative and quantitative information from the key staff:
  – face to face individual interview
  – after action reviews
  – post donation staff surveys

Huddle: Interdisciplinary care-planning meeting

The purpose of the huddle is two-fold:

a) To discuss ongoing clinical management of the patient and not to decelerate care until the family has an opportunity to make a decision about donation.

b) To identify who would be the best person(s) to approach the family (effective requestor). It is vital to identify the right time to approach the family and how to answer questions relative to donation.

A CMS and Joint Commission requirement
Are mutually agreed upon
• Timely referrals are to address both Brain Dead and DCD donors
• Clinical triggers are developed to identify potential donors
• Also include tissue triggers

• Can occur at anytime
• Needs all disciplines involved with patient care
• Everyone may not be present at the same time
• Everyone on the same page
1. At referral
   - medical suitability & plan
2. Prior to physician having the “bad news” conversation with the family
3. Prior to the approach
   - identify effective requestor
4. As needed

- Compile and update specific information for each hospital to develop or review at least annually
  - May include:
    - CMC provider number
    - Hospital address
    - Trauma center level
    - Services
    - # in-patient beds
    - # CC beds
    - Helipad access
    - Transplant hospital
    - Med. or Surgery residency program

Is a DCD P&P in place?

Yes
  - Review and ensure all staff understand P&P

No
  - Was DCD proposed before?
  - Any barriers?
  - Overcome barriers: lack of service to families, Joint Commission requirements
  - Option of transfer and protocols
  - Implement DCD policy
  - DCD Education

- Referral activity
- Organ and tissue dashboards
- Peer-comparison dashboards
- National data reports
- Group or subject specific reports
- Donor case outcome reports
- Donation Development Plans
- Medical record review (findings)
- After action review (findings)
• Data helps in development of supportive relationships with those who are critical in overall success.
  – Allows discussion, input into trend identification & hypothesis development
  – Strategy development for action
  – Allows a tailored plan to suit the situation
  – Data is the truth
  – Data is objective

• Eligible Death:
  Defined as the death of a patient 70 years old or younger who ultimately is legally declared brain dead (state law) and has no contraindications to donation and transplantation.

  - ≤ 70 years
  - Medically Suitable
  - BD Declaration
  - ELIGIBLE
• **Imminent Neurological Death:**

Defined as a patient who is 70 years old or younger with severe neurological injury, requiring ventilator support, has an absence of at least three brainstem reflexes, is not declared brain dead and is medically suitable to be a donor.

\[
g \geq 70 \text{ years} + \text{Medically Suitable} + \text{Loss of at least three Brainstem Reflexes} + \text{NOT Declared} = \text{IND}
\]

• Identify hospital performance goals established by HRSA, Joint Commission, and OPO.

• Compare the hospital’s data to established goals.

• Utilize your MRR data to evaluate reporting compliance.

• Conversion Rate

<table>
<thead>
<tr>
<th>Actual Donors</th>
<th>Eligibles + DCD Donors + Non-Eligible Donors</th>
</tr>
</thead>
<tbody>
<tr>
<td>GOAL</td>
<td>( \geq 75% )</td>
</tr>
</tbody>
</table>

• Formulate a plan for the year, with appropriate stakeholders/leaders.

• The Donation Development Plan

• Increase Organ Donation

• Increase Tissue Donation

• Achieve 75% Conversion Rate

• Achieve 100% Referral Rate

• Identify Best Practices

• Maintain Increases

• Create, implement, and modify the hospital’s action plan based on data collection.

• Determine what level of authority is necessary to implement the plan.

• Utilize performance goals to establish or modify an action plan.

• Document the strategic plan for endorsement by upper level management.

• Periodically reevaluate implementation of the strategic plan and modify if necessary.
• QA process of referrals
  – Timeliness of referral
  – IND criteria met
  – Family decline outcomes / unidentified approaches

• Identify missed opportunities
  – Missed Eligibles
  – Missed Imminent Neurological Deaths
  – Missed DCDs
  – (Missed Referrals)

• Hospital’s vs OPO’s perspective
• Variances in perspective
• Variance in process
• Comments & Acknowledgement/Recognition

• Review referral activity at each hospital with the aide of
  • Reports from call center
  • Medical records

• Determine whether all:
  • Deaths were reported
  • Cardiac deaths were reported in a timely manner
  • Imminent deaths were reported
  • Where organ referrals made within parameters of clinical triggers for brain death and DCD potentials
  • Quality control gathered data, e.g. eligibility
  • Identify missed referrals

• Real time Hospital Services
• Discussion of case with all involved
• Process improvement action plan per variance
• Tracking trends in variances
• Mutual accountability and partnership
• Follow-up
• Recognition and acknowledgements

• Conduct MRRs
  – aka. Death Record Reviews (DDR)
  – Identify critical elements to assess in the Medical record
  – Include: hospital unit, date and time of referral, patient demographics, cause of death, and outcome
  – Document critical data on an evaluation tool
  – Generate and provide a report that reflects the data outcome to share with each hospital and OPTN.
  – Use the data to develop your strategic HS plan for the hospital

Valuable Partnerships
• Implement donation process
• Refine donation process
• Create a culture of collaboration
• Create a culture of accountability
• Create and maintain a consistent visual hospital presence.

• Defined performance goals
• Senior administration involvement
• Mission and data driven decision making
• Develop integrated relationships
• Develop hospital based education

Successful Hospital Services = Hospital Ownership
• Starts with senior leadership
• Hospital accepts accountability for its role in all aspects of the organ and tissue donation process
• Disseminated throughout all hospital employees
• Benefits the donor and transplant community
• Donation becomes embedded in the hospital culture.

• You are the face of your OPO
• Cases run more smoothly when hospital takes ownership
• You are present many, many, many hours
• Your interactions determine perceptions
• You perform hospital services
• Perception = Reality
• Foster what you would like to receive

• Business Attire / Scrubs (clean and tidy)
• Hygiene
• Hair
• Name Badge

• ALWAYS introduce yourself – charge nurse, bedside nurse, if available ICU manager, physician, social worker, etc.
• Handshake – firm and confident
• Business cards
• Cell-phone (vibrate, designated areas)
• Never assume – ALWAYS ASK!
• Families of varying cultures and religions
  – Help the hospital staff to understand the cultural differences of the family
  – Don’t make assumptions
  – Accept differences and learn from them
• Hospital staff of varying cultures and religions
  – Don’t make assumptions
  – Seek to genuinely understand their viewpoints
  – Be open to learn from them and kindly answer questions
  – Don’t try to “convert”, just seek to gain their support for the family

• A Common Goal
• A Strong Commitment
• Our Resources
• The Puzzle
Objectives

At the completion of this presentation, the participant will be able to discuss the basic principles of the following:
- Donor stability in relation to the OR
- The required surgical personnel and their specific roles during the recovery
- Sterile and aseptic requirements
- Organ preservation
- Required documentation
- Proper packaging and labeling of all organs and specimens

Donor Alliance

Four Transplant Programs in Colorado
- University of Colorado
- Centura Porter Adventist Hospital
- Presbyterian/St. Lukes Medical Center
- The Children's Hospital

Square Miles = 200,000+
Population = 5 million
Acute Care Hospitals = 67
Critical Access Hospitals = 40

The OR . . . The Land of Blue

- For many ORCs, the OR is a source of anxiety and stress—it's foreign territory
- It's all about finding the courage to get out of your comfort zone to experience personal and professional growth

Donor Alliance Staff

- 1 Director of Organ Procurement
- 2 Clinical Supervisor
- 9 Full Time Organ Recovery Coordinators
  - 3 Levels of ORC
- 4 Full Time Organ Recovery Specialists
  - 2 Levels of ORS
- 1 Organ Administrative Assistant

Be Prepared...

- Use and follow check lists
- Listen to and follow those that have been there before
- Know your OPO SOPs and follow them
  - OPTN/UNOS policies
  - CMS standards
  - AOPO standards
Donor Stability

- Ensure all equipment is available for transportation to the OR
  - Transport monitor: HR/BP/sats
  - Maintain IVFs and pressors
    - IV and pressors bags full?
  - Portable vent or bag ventilation
    - PEEP valve, full O2 tank
  - Protect all IV/catheters
    - PA line, A-line, foley, etc

Surgical Personnel/Supplies

- RN Circulator
  - Review death note and consent
  - Proper ID of the donor and procedure
    - Takes place during “Time Out” with surgeon prior to incision
  - Specific needs (answering MDs pagers, pathology, equipment, pt. positioning)
  - Name and credentials of recovery staff
  - Time frame

Donor Stability

- Transport to the OR
  - Bedside report to anesthesia
  - Bring all paperwork, hospital chart and pt ID plate/stickers
  - Prepare for the worst, hope for the best
    - emergency drugs
  - Family comes first
    - May need more time before moving
    - Surgical team/anesthesia can wait

Surgical Personnel/Supplies

- Surgical Tech
  - Specific surgeon needs or requests
  - Set up of back table
    - One (or more) back table for organ packaging supplies, another for instrumentation, extra basins
  - Assists with packaging of typing material and organs
  - Learn his/her name and be gracious

Surgical Personnel/Supplies

- Anesthesia (AOPO requires written guidelines)
  - Review goals of management
    - Important if doing lungs
      - Keep lungs dry, continue to ventilate after x-clamp, vent settings as per surgeon request
  - Medication needs or restrictions
    - Paralytics, heparin, Mannitol, etc
  - Special needs
    - Labs, blood tubes, betadine down the NG, etc
  - Obtain copy of anesthesia record

Donor Positioning

- Arms tucked or extended
- EKG leads lateral or posterior
- Clean shave of incision site
- Full thoracic and abdominal prep
- Foley bag at head of bed
- Cautery/Bovie grounding pads
- Pediatric cases, place a roll under the shoulders to extend the neck
**Surgical Personnel/Supplies**

- The bigger the OR the better
- At least two back tables are preferred
- Thoracotomy set with sternal saw or Lebsche knife
- Sternal retractor
- Large Balfour retractor
- Slush
- Suction (two Poole suckers)

---

**Back Table Setup**

- Number of tables needed: Generally one for heart, one for lungs and one for liver, kidneys and pancreas
- Basins: One each for heart, lungs, liver; kidney and pancreas can share
- Packaging materials
- Back table flush supplies and equipment
- Instruments for organ inspection and dissection on back table

---

**8 Principles of Aseptic Technique**

1. Only sterile items are used within the sterile field.
2. Items of doubtful sterility must be considered unsterile.
3. Whenever a sterile barrier is permeated, it must be considered contaminated
4. Sterile gowns are considered sterile in front from shoulder to level of the sterile field and at the sleeves from 2 inches above the elbow to the cuff.

---

**Sterile/Aseptic Technique**

- Definition of Asepsis: absence of pathogenic organisms
- Aseptic practices based on premise that surgical infections are caused by exogenous microorganisms
- Aseptic technique developed to minimize the patient’s exposure to exogenous microbes

---

8 Principles of Aseptic Technique, Continued...

5. Tables are sterile only at table level
6. The edges of a sterile enclosure are considered unsterile
7. Sterile persons touch only sterile items or areas; unsterile persons touch only unsterile items or areas
8. Movement within or around a sterile field must not contaminate the field.

---

**Sterile/Aseptic Technique**

- Assure proper prep of surgical surface
- Maintain aseptic technique when preparing all flush solutions and sterile ice/slush for body cavity
- Monitor for sterile technique throughout the procedure
  - Moving around back tables, contamination of personnel or supplies
- Inspect sterile packaging before opening onto sterile field

---

Recovery Teams

- Coordinate all communication between visiting teams
  - FBO, tail #, ground transport (2.5.7)
  - Special requests
    - Bronch, extra blood tubes/typing material, etc
  - Paperwork (2.5.6.1)
    - ABO source docs, serologies, med/doc, consent, donor evaluation, complete donor record, and organ quality record
  - Additional information as requested
    - Copies of echo, cath, CXR, etc
  - Proof of Surgeon credentials (AOPO portal)

Inside the Chest

- Cannula placement for the heart is in the aortic-root
- Cannula placement for the lungs is in the pulmonary artery
- X-Clamp is placed distal to the aortic root
- Vena Cava is incised after x-clamp to allow for venous drainage

Surgical Procedure

- Exploratory lap and Thoracotomy
- Placement of retractors; sternal and abdominal
- Dissection of abdominal and cardio-thoracic organs will proceed simultaneously
- Set up and priming of perfusion lines

Inside the Abdomen

- Visualization of the liver
- Texture, color, lesions
- Venous cannula placement is in the portal, IMV, or splenic (pre-cool, portal flush)
- Aortic cannula placement is in the aorta proximal to the iliac bifurcation
- Aortic x-clamp placement is supra celiac
- Venous drainage is in the chest cavity or the IVC at the level of the iliac bifurcation

Inside the Chest

- Sternum opened with saw. Sternal retractor placed to hold sternum open.
- Pericardium opened
- Heart & coronary arteries are inspected
- Lungs are inspected and the pleura incised

Cross Clamp

- Sterile slush dispensed to field
- Heparin given 5-10 minutes prior to X-clamp
- All teams agree they are ready
- OR and perfusion staff are ready
- Document the X-clamp time
- Notify transportation for outside teams
Organ Preservation

- Begins with good donor management
- Follows with good communication
- Ends with well-perfused organs
- Provides immediate function, making the recipient’s post-op course as uncomplicated as possible

Preservation Solutions Should...

- Displace blood and prevent clotting
- Prevent cellular swelling
- Provide substrates
- Stabilize cell membranes

Goals of Preservation

- Extended organ viability
- Organ function after transplant
- Methods of preservation are simple, reproducible and easily applied
- Benefits the recipient

Types of Preservation Solutions

- Euro-Collins
- Viaspan UW (Belzer’s)
- HTK
- Variety of kidney pump solutions

Organ Preservation

- Hypothermia slows metabolism and oxygen consumption

- Preservation methods attempt to minimize catabolism and support anabolism
  - Dynamic
  - Cold

Organ Preservation

- Be prepared
  - Cannulae/tubing per surgeon preference
  - Sterile frozen saline ready and available
  - Cold preservation/storage solutions
    - These are OPO/TXC specific
**Heart Perfusion**
- Cardioplege, UW, or Celsior solution arrests the heart (1-2 liters)
- Once preservation begins slush\cold saline placed into cavity
- Max cold time 4-6 hours (TXC specific)

**Pancreas Perfusion**
- Solution is TXC specific
- No direct perfusion
- Can become over-perfused very easily
- Back table flush
- May do arterial reconstruction at this point
- Cold time 6-12 hours
- Recover vessels to go with pancreas

**Lung Perfusion**
- Pulmoplegia or Perfadex(1-4 liters)
- Cold saline or slush into cavity
- Max cold time = 4-6 hours (or longer)
- Some programs may do a retrograde flush on the back table to flush out any potential blood clots
- Many programs use Prostaglandin E

**What about the Pancreas?**
- Inspection of the pancreas for calcification and fatty changes
- No direct cannula placement
- Clamp placement and venous drainage are the same as the other abdominal organs
- A section of the duodenum and spleen are recovered with the pancreas

**Liver Perfusion**
- Perfused through abdominal aortic cannula
- Solution and volume is TXC specific
- Flush quality is gauged by the clarity of effluent
- Max cold time could be up to 24 hours on healthy, well perfused organ; preferred time is <12 hours

**Kidney Perfusion**
- Dissection to separate will be done on back table if kidneys are removed en bloc
- Geroder’s fascia will be trimmed to allow examination of the kidney surface
- Back table flush will be performed if needed to clear any retained blood
Kidney Anatomy

- Identification of the ureters early on is important
- Inspection is done on the back table
- Aortic cannula placement is the same as the liver
- Venous drainage is also the same

Documentation of Recovery

- Organ Data
  - Flush times/characteristics
  - Flush/storage solutions and volumes
  - Anatomy
  - Kidney measurements
  - Reasons why organs not recovered

Documentation of Recovery

- Times documented (everyone involved agree on ONE source for the times)
  - Enter OR
  - Incision
  - X-clamp
  - Time each organ recovered
  - Administration of heparin and other meds

Vessels and Tissue Typing

- Iliac vessels are recovered for re-anastomosis of liver & pancreas. (UNOS 5.7)
- Recovered after all organs are removed
- Lymph nodes and spleen are recovered by the transplant center for tissue typing.
  - 3 to 5 lymph nodes
  - One 2 X 4cm wedge of spleen
  - Required for kidneys and pancreas (2.5.4)
  - Archived at Host OPO histocompatibility lab

Documentation of Recovery

- Information Documented
  - Average/high/low BP, HR, UOP
  - Fluids/meds given
    - Blood products, crystalloids, pressors, etc
  - Personnel involved (OR staff and teams)
  - Biopsy results

Specimens/Labels/etc

- UNOS Policy 5.0-5.6 and 2.5
  - Specimen collection and storage
  - Standard labeling specifications
  - Documentation (ABO and paperwork)
  - Standard organ package specifications
  - Transportation responsibility
Shipping Organs

- Moisture resistant wax impregnated fiber outer container
- Box—Red bag—Styrofoam box—garbage bag—ice—organ—ice
- Typing materials & blood must be in leak proof plastic bags at ambient temperature
- Donor paper work in waterproof bag
- Blood & paperwork must accompany all organs, typing material required for kidneys and pancreas

Pulsatile Perfusion Disadvantages

- Increased costs (up front)
  - Lab construction
  - Equipment purchase
  - Staff training
- ?? Endothelial injury
  - Unknown just how much can occur
- Potential equipment failure

Pulsatile Kidney Perfusion

An Old Procedure; Revisited, Revised, Reinvented

Pump Parameters

- Pump parameters vary according to manufacturer
- Maintain temp 4-8 degrees C
- Goals of RMP
  - Increased flow rates over time
  - Decreased resistance over time

Pulsatile Perfusion Advantages

- Better long term preservation (esp. >24 hrs)
- Ability to monitor resistance & thus predict function
- Ability to manipulate flow with chemotherapy
- Increases high energy phosphate stores within the kidney
- Removes (or dilutes) products of ongoing metabolism
- Maintains ‘dilated’ vasculature, i.e. avoids vasoconstriction

Flow Rates During Pulsatile Perfusion

- <80 is poor
- 80-100 is moderate
- > 100 is excellent
Pump Conclusions

- Preservation modality can impact greatly on initial graft function; (all OPOs to develop capability to pump kidneys by mid-2008 per UNOS)
- Delayed graft function can be reduced with pulsatile perfusion/preservation
- Machine preservation is the treatment of choice for expanded criteria kidneys and most DCD kidneys

Final Thoughts

- Good communication is key!
- Be organized, be informed
- Know UNOS policies and your SOPs
- Foster positive OR relationships
- Keep the donor family and their wishes in mind
- Learn from those who’ve gone before you and reach out to those that follow

Questions?

Thank You!

Email: frathman@donoralliance.org
Physical Assessment

Getting Back to the Basics

- **Airway**
  - ETT in place, secure, air leak?
- **Breathing**
  - Ventilating appropriately
  - O2 saturation
- **Circulation**
  - Hemodynamics
  - Tissue perfusion

Head-to-toe

- Developing a standard assessment of the patient will eliminate omission
- Full exposure - head to toe (and keeping them warm while doing it)
- Inspection
- Palpation
- Auscultation
- Percussion
- Please don’t forget the back
Auscultation...some only do this step?

- Anterior, posterior & lateral (compare right to left)
  - Note adventitious sounds
- Decreased breath sounds AND dullness is fluid
- Decreased breath sounds and hyperresonance is pneumothorax
- Decreased breath sounds and normal percussion is atelectasis

Auscultation

- Identify S1 & S2

  - Are the heart sounds muffled?

Auscultation

- Bowel sounds
  - Normal?
  - Decreased?
  - Absent?
Story: Character drowns
In Hospital: Declared Dead
Errors: Mother character asked to “withdraw” support

Message to the public:
Dead isn’t really dead!

Harvard Medical School Ad Hoc Committee
Criteria for Brain Death, 1968

- Unreactivity and unresponsivity
  - no response to externally applied stimuli
- No movements or breathing
  - 1 hour observation
  - 3 min off respirator if PCO₂ normal at start
- No reflexes
- Isoelectric electroencephalogram
  - 10 - 20 min record, 5 - 10 µV/mm
  - use 2.5 µV/mm for a period of 5 - 100 sec
- No hypothermia (< 32.2°C)
- No CNS-depressant drugs
  - “All of the above tests shall be repeated at least 24 hours later with no change”

If it is not done to a standard ...

American Academy of Neurology Guidelines

- Published in 1994-5 and revised this year
- An attempt to provide an authoritative overview on determination of brain death
- Overall accepted by the medical community

If it is not done to a standard ...

American Academy of Neurology Guidelines

- Evidence-based guideline update: Determining brain death in adults
  - Signed by the Quality Standards Subcommittee of the American Academy of Neurology
  - Published in Neurology
  - Available at [link]
AAN Guidelines

• Overview
  – irreversible loss of function of the brain, including the brainstem
    • Neurological: severe head injury or aneurysmal subarachnoid hemorrhage
    • Medical/Surgical: hypoxic-ischemic brain insults and fulminate hepatic failure

• Justification
  – need for standardization of the neurological examination criteria
  • differences in clinical practice in performing the apnea test
  • controversies over appropriate confirmatory laboratory tests

AAN Guidelines

• Prerequisites
  – Clinical or neuroimaging evidence of an acute CNS catastrophe that is compatible with the clinical diagnosis of brain death
  – Exclusion of complicating medical conditions that may confound clinical assessment (no severe electrolyte, acid-base, or endocrine disturbance)
  – No drug intoxication or poisoning
  – Core temperature ≥ 36°C (96.8°F)

An Anatomical Review
Brain Stem

**Midbrain**
- Cranial Nerve III
  - pupillary function
  - eye movement

Brain Stem

**Pons**
- Cranial Nerves IV, V, VI, VII
  - conjugate eye movement
  - corneal reflex
  - facial movement

Brain Stem

**Medulla**
- Cranial Nerves IX, X
  - Pharyngeal (Gag) Reflex
  - Tracheal (Cough) Reflex
- Respiration

Reticular Activating System

- Receives multiple sensory inputs
- Mediates wakefulness

AAN Guidelines: EXAM

- Exam: three cardinal findings in brain death
  - coma or unresponsiveness
  - absence of brainstem reflexes
  - apnea

The E

- Coma or unresponsiveness
  - no cerebral motor response to pain in all extremities
  - nail-bed pressure
  - supraorbital pressure
The Exam: Brainstem Reflexes

• Absence of brainstem reflexes
  
  • Pupils
    - i. No response to bright light
    - ii. Size: midposition (4 mm) to dilated (9 mm)
  
  • Ocular movement
    - i. No oculocephalic reflex (testing only when no fracture or instability of the cervical spine is apparent)
    - ii. No deviation of the eyes to irritation in each ear with 50 ml of cold water (allow 1 minute after injection and at least 5 minutes between testing on each side
  
  • Facial sensation and facial motor response
    - i. No corneal reflex to touch with a throat swab
    - ii. No jaw reflex
    - iii. No grimacing to deep pressure on nail bed, supraorbital ridge, or temporomandibular joint
  
  • Pharyngeal and tracheal reflexes
    - i. No response after stimulation of the posterior pharynx with tongue blade
    - ii. No cough response to bronchial suctioning

Oculo-cephalic Testing

Cold Caloric Testing

Pupillary Exam

The Exam: Brainstem Reflexes

• Absence of brainstem reflexes
  
  • Pupils
    - i. No response to bright light
    - ii. Size: midposition (4 mm) to dilated (9 mm)
  
  • Ocular movement
    - i. No oculocephalic reflex (testing only when no fracture or instability of the cervical spine is apparent)
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  • Pharyngeal and tracheal reflexes
    - i. No response after stimulation of the posterior pharynx with tongue blade
    - ii. No cough response to bronchial suctioning

NATCO
The Exam: Brainstem Reflexes

- Absence of brainstem reflexes
  - Pupils
    - i. No response to bright light
    - ii. Size: redposition (4 mm) to dilated (5 mm)
  - Ocular movement
    - i. No oculocephalic reflex (testing only when no fracture or instability of the cervical spine is apparent)
    - ii. No deviation of the eyes to irrigation in each ear with 50 ml of cold water (allow 1 minute after irrigation and at least 5 minutes between testing on each side)
  - Facial sensation and facial motor response
    - i. No normal reflex to touch with a throat swab
    - ii. No jaw reflex
    - iii. No grimacing to deep pressure on nail bed, supraorbital ridge, or temporomandibular joint
  - Pharyngeal and tracheal reflexes
    - i. No response after stimulation of the posterior pharynx with tongue blade
    - ii. No cough response to bronchial suctioning

The Exam: Apnea Testing

- Positive Test: Supports Brain Death
  - respiratory movements are absent
  - arterial PCO2 is ≥ 60 mm Hg *(option: 20 mm Hg increase in PCO2 over a baseline normal PCO2)*
- Negative Test: Does Not Support the Clinical Diagnosis of Brain Death
  - respiratory movements are observed
  - the test should be repeated

Ancillary Testing

- Conventional angiography
  - No intracranial filling at the level of the carotid bifurcation or circle of Willis
  - The external carotid circulation is patent, and filling of the superior longitudinal sinus may be delayed.
- Electrocorticography
  - No electrical activity during at least 30 minutes of recording that adheres to the maximal assessment criteria
  - EEG recorded in suspected brain death as adopted by the American Electroencephalographic Society
- Transcranial Doppler ultrasonography
  - Ten percent of patients may have normal temporal bone windows. Therefore, the initial absence of Doppler signals cannot be interpreted as consistent with brain death.
  - Small systolic peaks in early systole without diastolic flow or reverberating flow, indicating very high vascular resistance associated with greatly increased intracranial pressure.
- Technetium-99m hexamethylpropyleneamine oxime brain scan
  - No uptake of isotope in brain parenchyma ("hollow skull phenomenon")
- Somatosensory evoked potentials
  - Bilateral absence of N20-P22 response to median nerve stimulation
  - The response should adhere to the minimal technical criteria for somatosensory evoked potentials as adopted by the American Electroencephalographic Society

Documentation

- Etiology and irreversibility of condition
- Absence of brainstem reflexes
- Absence of motor response to pain
- Absence of respiration with PCO2 ≥ 60 mm Hg
- Justification for confirmatory test and result of confirmatory test
- Repeat neurologic examination. *(option: the interval is arbitrary, but a 6-hour period is reasonable)*
Pitfalls in the Determination

- Severe facial trauma
- Preexisting pupillary abnormalities
- Toxic levels of any sedative drugs, aminoglycosides, tricyclic antidepressants, anticholinergics, antiepileptic drugs, chemotherapeutic agents, or neuromuscular blocking agents
- Sleep apnea or severe pulmonary disease resulting in chronic retention of CO2
AIRWAY AND PULMONARY MANAGEMENT

Objective

- Develop critical thinking skills as it relates to the airway and pulmonary management of the brain dead organ donor

Origins of Mechanical Ventilation

- Negative-pressure ventilators ("iron lungs")
  - Non-invasive ventilation first used in Boston Children’s Hospital in 1928
  - Used extensively during polio outbreaks in 1940s – 1950s
- Positive-pressure ventilators
  - Invasive ventilation first used at Massachusetts General Hospital in 1955
  - Now the modern standard of mechanical ventilation

Skills to Demonstrate in this session:

- Identify basic ventilator settings and readings
- Describe the findings on a standard chest radiograph
- Identify basic pulmonary derangements of the organ donor
- Recognize and treat common pulmonary abnormalities affecting the organ donor

A word about terminology...

- Oxygenation: The process of transferring oxygen to the red cells and the tissues
- Ventilation: The process of removing CO2 from the body via the lungs
- Respiration: This occurs at the cellular level and is a biologic process involving the utilization of oxygen and electron transport within the 'cellular machinery' of the mitochondria.

Goals of Mechanical Ventilation:

- To provide adequate oxygenation and ventilation without doing damage (barotrauma or atelectasis).
- Keep the GOALS of mechanical ventilation in mind and the mode of ventilation should not matter much
Modes of Ventilation (alphabet soup!)

- Most clinicians get comfortable with one mode of ventilation and USE it! You must have a familiarity with the basics of ALL modes of ventilation and their differences.
- Resist the temptation to label one as ‘good’ versus ‘bad’.
- A ‘good’ mode used inappropriately may be ‘bad’ and vice-versa.

Basic means of providing ventilation:

- Volume-cycled
  - SIMV, CMV, AC
- Pressure-cycled
  - PC, PRVC, APRV, Bi-Level

Additional details to pay attention to...

- Pressure is reported in cm of H₂O
- Peak Inspiratory Pressure (PIP)
  - < 20 no more than 35
- Plateau Pressure
  - < 30
- Mean Airway Pressure (MAP)
  - Area under the pressure/time curve during inspir/expiration
  - < 15 nor more than 25

Basics

- Volume-cycled
  - Designed to deliver a set volume
  - Pressure can vary based on the mode and the patient’s lung compliance
- Pressure-cycled
  - Designed to deliver a set pressure
  - Volume can vary based upon the mode and patient compliance

More details......

- Tidal Volume (Vt)
  - 6-8cc/kg (what is your practice??)
- PEEP (minimum 5...why not higher??...push to 8, 15)
- Minute Ventilation (Resp. Rate * Vt)
  - Ideally 10-15
- I:E Ratio (this can be a nugget in your pocket)
- Sensitivity (turn it down)
  - Flow or Pressure
What is Auto-PEEP?

- Normally, at end expiration, the lung volume is equal to the FRC
- When PEEPi occurs, the lung volume at end expiration is greater than the FRC

Compliance

\[ C_{\text{static}} = \frac{V_t}{(P_{\text{plat}} - \text{PEEP})} \]

Normal \( C_{\text{static}} \) 50-100 cc/cmH₂O

Increased PIP & Plateau
- ↑ Tidal Volume
- ↑ Compliance
  - Edema/ARDS
  - Effusion
  - Pneumothorax
  - Ascites, IAH

Increased PIP & Preserved Plateau
- ↑ Increased Flow Rate
- ↑ Airway Resistance
  - Kinked/Obstructed ETT
  - Bronchospasm
  - Secretions

Complications

- This \( P_{\text{plat}} \) is split and therefore represents a Resistance To AirFlow problem brought on by bronchospasm.

Case Study

PiP’s are elevated from 22cmH₂O to 48cmH₂O

You auscultate the patient’s breath sounds and note diffuse tight expiratory wheezing.

What is causing her PiPs to rise?
- Compliance Problem due to “Stiff Lungs”?
- Resistance Problem due to Bronchospasm?

What can you do to determine the cause?
What can you do to fix the problem?

Complications

- PiP’s are elevated from 22cmH₂O to 48cmH₂O
- (f) 12
- VT 10ml/kg
- PEEP 5
- FiO2 1.0
- I:E 1:2

Mode (ACV)

VT 10ml/kg
PEEP 5
FiO2 1.0
I:E 1:2

How can we fix it?
Complications

You auscultate the patient’s breath sounds.
And note clear but distant breath sounds.

What is causing her PIPs to rise?
Compliance Problem due to “Stiff Lungs”?
Resistance Problem due to Bronchospasm?
What can you do to determine the cause?
What can you do to fix the problem?

Mode (A/)
(I.12)
VT 8 cc/kg
PEEP 5
FIO2 0.5
I:E 1:2

Complications

This P_plat is elevated and therefore represents a Compliance problem brought on by “Stiff Lungs”.

How can we fix it?

Respiratory Physiology

How to think of donor lungs:

Party Balloons!!!
- If they don’t have enough air or if they pop, it’s not a good thing...
- Not enough air: Atelectasis
- Too much air: Barotrauma

The ventilator’s okay. Now what?

- Check an ABG initially and often if needed
- Goal is for all parameters to be WNL
- Better to be acidotic than alkalotic

EtCO₂

Capnography is mechanical link to perfusion
Provides more than proper ETT placement
Don’t forget the CXR

- Look at the same 6 things (IN THIS ORDER) on EVERY CXR YOU LOOK AT
  - Soft tissues
  - Bones
  - Mediastinum
  - Diaphragms
  - Support Lines
    - Central lines, PA Catheter, ETT, Enteral tube, CTs
  - **Pulmonary parenchyma LAST!**

---

Lung Volume Recruitment

- MAP and FRC** are proportional
  - As the MAP increases, alveoli are recruited to increase surface area, and ultimately PaO₂
  - This can be achieved by PEEP, increased i time, or inverse ratio ventilation

**FRC=Functional Residual Capacity

---

Pulmonary Management

- Pulmonary hygiene
  - Good oral care, keep secretions removed from above cuff
  - Inflate cuff to 25 cm H₂O
  - Suction q 1-2 hrs
  - Turn patient q 1-2 hrs if VS tolerate, consider proning (360° protocol)
  - CPT/Auto beds
  - HOB >30°
- Respiratory treatments
  - Albuterol or MDI q 2-4 hrs
- Bronchoscopy
- Lung recruitment (check volume status)
  - What is your protocol?

---

Common ‘Life’ threatening derangements and their treatment

- RMS intubation
- Tension Pneumothorax
- Pulmonary Edema
- Hemothorax
- High mean airway pressures and hypotension / hypoxemia
  - Pull back the tube
  - Needle thoracostomy and chest tube
  - Diuresis
  - Chest tube; transfusion
  - Identify and treat the condition (QUICKLY)
    - Mucous plugging, ventilator settings too high, ptx, air trapping, etc...
Become Be Friends with Respiratory Therapy!

- Spend time developing game plan with RT
- Help them to understand the impact they could have on someone’s life today
- Explain to them your needs for not only diagnostic testing but frequent changes
- Provide simple tool to help explain needs
Vasopressors

**Alpha Physiology**
- stimulation of alpha-1
- vasoconstriction
- increased BP
- decreased CO

**Beta Physiology**
- stimulation of beta-1
- increases: CO, HR, myocardial oxygen demand
- stimulation of beta-2
- decreases BP, PCWP

---

Dopamine

- **Low dose** 1-3 mcg/kg/min
  - stimulation dopaminergic receptors
  - dilates renal arteries
  - increases urine output
  - some + inotropic activity
- **Moderate dose** 5-10 mcg/kg/min
  - predominantly beta effects
  - increases CO, HR
  - slight increase: BP, PCWP
  - slight decrease: SVR
- **High Dose** 10-20 mcg/kg/min
  - alpha and beta stimulation (renal vasoconstriction)
  - increases: HR, BP, PCWP, SVR
  - decreases CO (increased work load)

---

Phenylephrine (Neosynephrine)

- **Pure alpha**
  - increases BP, SVR, PCWP
  - may decrease renal perfusion at higher doses

Norepinephrine (Levophed)

- **Alpha effects**, with some **Beta-1**
  - Most potent vasoconstrictor
  - Increases BP, SVR, PCWP

---

Epinephrine

- **Stimulated both alpha and beta receptors**
- **Use in refractory hypotension** to dopamine/dobutamine
- **Low dose**: 0.01-0.05 mcg/kg/min
  - beta 1>beta 2
  - increase CO, HR
  - decrease SVR, PCWP
- **High Dose**: > 0.05 mcg/kg/min
  - alpha and beta effects
  - increases BP, PCWP, CO, SVR, HR
  - potential to decrease urine output

---

Dobutamine (inotrope)

- **Increases contractility** through direct action on B-1 receptors
  - Efficiency is dependent upon presence of adequate number of beta receptors, which may be down-regulated in chronic heart failure (not as likely in the donor population)
  - Improves oxygen deliver to the tissues
  - Decreases PCWP, SVR
  - Usually minimal effects on BP and HR

---

Milrinone (inotrope) (Phosphodiesterase inhibitor)

- **Increases contractility**, by providing afterload reduction and increasing diastolic relaxation
- **Pulmonary vasodilator**
- Not dependent on adequate number of alpha or beta receptors to create its action on the heart
- If the patient is vasodilated already it can cause hypotension
Hemodynamics & Resuscitation

Objective

- Develop critical thinking skills as it relates to the hemodynamic monitoring and resuscitation of the brain dead organ donor

Skills to Demonstrate:

- Interpret key volume sensitive indicators
- Properly identify the cause(s) of hemodynamic instability
- Articulate the intervention(s) to correct the cause of the instability
- Recognize when endpoints of resuscitation have been achieved
- Demonstrate ongoing assessment of the hemodynamic status of the donor

Basic Circulatory Physiology

- Essentially a system of 3 components:
  - Capacitance vessels (Venous/Preload)
    - What do you have in the tank? How much fluid do you have in the heart before it beats?
  - Resistance vessels (Arterial/Afterload)
    - What type of squeeze do you have? What is the resistance the heart is pumping against?
  - Hydraulic Pump (Cardiac)
    - How much fluid is being pumped with each beat?

- When assessing what aspect of the circulatory system you are dealing with it is important to:
  - know the history of the patient
  - mechanism of injury
  - what has happened to them since admission

Evaluation of Hypotension in the Brain Dead Organ Donor

- Hypovolemia (Capacitance/Venous)
  - Absolute
    - Injury
    - ICP Management
    - Hyperglycemia
    - DI
    - Hypothermia
  - Effective
    - Venodilatation
      - Loss of tone causing venous pooling
      - Rewarming
Evaluation of Hypotension in the Brain Dead Organ Donor

- Cardiac Dysfunction
  - Pre-existing disease
  - Injury
  - Brain death process
  - Metabolic depression
  - Volume overload (CHF)
  - Arrhythmias

Indicators of pump function

Physical Assessment
- Color/temperature
- JVD

Hemodynamic Parameters
- Cardiac index (2.5-4.2)
  - Good rule is that C.O. is double
- LVSWI (Left ventricular stroke index) (44-56)
  - Amount of work to eject blood out of LV

Additional Testing
- Bedside sono
- Echocardiogram/TEE

Evaluation of Hypotension in the Brain Dead Organ Donor

- Vasodilation (afterload)
  - Spinal shock
  - Catecholamine depletion
  - Loss of vasomotor tone/autoregulation
  - Acquired sepsis

Indicators of resistance

- Mean Arterial Pressure (80-100)
- Systemic Vascular Resistance (1200-1500)
  - What is the resistance the heart has to pump against to circulate blood?

Indicators of Volume

- CVP (3-8)
  - Amount of blood returning to the heart
- SVV (9-11) “High is dry”
  - Indicator of preload responsiveness
  - Swing in arterial pulse pressure
- PCWP (6-12)
  - Indicator of volume in the left side of the heart
- Pulses Paradoxus
  - Amount of variability of the arterial tracing

Know the limitations of your monitoring...

CVP…not what it was once believed??

If using SVV, arrhythmias impact that reading

Bottom line…they are tools…
…ALWAYS look at your patient!
Interventions
- Capacitance (Preload) Issues
  - Volume
    - Crystalloids
    - Colloids
    - Blood products
  - Glucose control
  - ADH replacement (DDAVP, Vasopressin)
  - Warming methods

Anatomy of body fluid compartments
- Varies by function of body size, age, wt. and sex though relatively constant
- Total Body Water: 50 - 70% total body weight
  - ~60% for males, ~50% females
- Fat contains little water
- Fluid is in three compartments
  - Intracellular, Extracellular, transcellular

Interventions
- Pump issues
  - Inotropes (Milrinone/Dobutamine)
  - Rate control
    - Epinephrine/isuprel/Pacemaker
    - Beta blockers
  - Electrolyte replacement (K, Mg, Ca)
  - Correct acid/base balance
  - IABP

‘Anatomy’ of body water

Classification of Body Fluid Changes
- Volume changes
  - Addition or subtraction of isotonic solution
- Concentration changes
  - Addition or loss of water alone from the extracellular fluid
- Compositional changes
  - Change in the concentration of ions within the EC fluid without significant change in the total number of osmotically active particles
  - Such as electrolytes
- Distributional changes
  - E.g: internal loss of EC fluid into a non-functional space (results in the contraction of the functional EC space
- Mixed Volume and Concentration Abnormalities
Classification of Fluids

<table>
<thead>
<tr>
<th>Hypotonic</th>
<th>Isotonic</th>
<th>Hypertonic/Colloid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rapidly enters 3rd space</td>
<td>Equally equilibrates</td>
<td>Stays in vessels</td>
</tr>
<tr>
<td>D5W, 0.25 NS, etc.</td>
<td>LR, Etz.</td>
<td>NS, Hespan/Albumin, Blood</td>
</tr>
</tbody>
</table>

Resuscitation thought process...
- Hypervolemic, hypovolemic or euvolemic?
- *Where* is the fluid excess/deficit? (Intracellular, intravascular, interstitial?)
- Concentration changes?
- Composition changes?
- Where does it go when you put it in?
  - Isotonic
  - Hypertonic
  - Hypotonic

When is enough, enough?
- Stability is achieved
  - Stable BP, HR, O2Sat, UO, lactate, BE
- Ongoing assessment to assure ongoing stability!