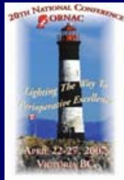
Regulations for Donation & Transplantation

The Impact Factor for Perioperative Practice



Transplantation is playing an increasing role in treating patients with end stage organ/tissue function

- Organ donation has high profile in the health care sector
- Most Canadians support organ/tissue donation
- Tissue donation appears to have lower public awareness

Significant medical advances have resulted in remarkable success and survival rates for organ & tissue recipients. However the rates of donation have not kept pace with demand resulting in a critical shortage of available healthy organs & tissue.

Objectives….

- Provide brief description of donation process
- Provide Perioperative perspective
- Provide overview and impact of Health Canada Regulations
- Provide overview of CSA Standards
- Present current national initiatives and advances in practice

The process of organ/tissue donation is complex and relies on multiple parties working in concert toward common goals.

Donation Process

1. Identification & Referral
2. NDD
3. Consent
4. Assessment
5. Donor Management
6. Placement / Allocation
7. Retrieval
8. Transplantation

Donor Identification & Referral

Donor Identification & Referral

- Usually identified in an ICU environment or through the ED
- Common triggers for referral include: severe acute brain injury requiring mechanical ventilation, has clinical findings consistent with a GCS that is less than or equal to a mutually agreed upon threshold, is being evaluated for diagnosis of brain death, or has had withdrawal of life sustaining therapies

Donor Identification & Referral

- Any health professional can identify a potential donor.
- The detection of the potential donor is a team approach
- The responsibility does not lie on one single individual
- It may involve the bedside nurse, the resident, the physician and the in-house donor coordinator
- It is also largely dependent on the patient area in question (ICU, ER, nursing unit, palliative care unit)

Donor Identification & Referral

- Most provinces now have "required or routine notification"
- Hospitals/health care workers are legislated to notify OPO of death or imminent death of any patient

Types of Donors

- Living Donor
- Deceased (Cadaveric) Donor
  - Brain Dead (NDD)
  - Non Heart Beating

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Living Donation

- Any living person who makes an informed choice to donate an organ/tissue, usually between relatives or persons with close relationships
- Examples of tissue include blood or bone marrow
- Organs that may be donated include kidney, lobe of the liver or lung

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Deceased (Cadaveric) Donation

- Deceased donor is any person who has succumbed to cardiac or brain death
- May be an organ and/or tissue donor
- Causes of death may vary

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Criteria for Donation

Organ

- Brain Death
- Functioning Cardiocirculatory System
- On Ventilator

Or.....

- DCD

Tissue

- Cardiac or Brain Death
- Can be organ donor

Defining Tissue Donation

- Differs from organ donation
- Life-enhancing as opposed to life-saving
- Retrieval can take place up to 24 hours post-mortem
- Suitability criteria more strict

Age Limitations

- Chronological age of any potential donor should never preclude organ donation – organ quality must be evaluated for each individual donor.
- Age Criteria for tissue donors more specific

Relative Contraindications to Organ Donation

- Unknown cause of death
- Transmissible diseases **
- High risk behavior
- Septicemia
- Neurological diseases of unknown etiology
- Malignancy of organ
- Prolonged ischemia/ hypotension/ asystole
- Coroner's case

Absolute Contraindications for Tissue Donation

- Unknown cause of death
- HIV, Hep B, Hep C
- High Risk Behavior
- Neurological diseases of unknown etiology
- Active untreated sepsis
- Leukemias/Lymphomas

What Can Be Transplanted?

Perfusable (or solid organ)

- Heart
- Lungs
- Liver
- Pancreas (whole or islets)
- Kidneys
- Small Bowel

What Can Be Transplanted?

Tissues

- Ocular (corneas/sclera)
- Cardiovascular (valves, pericardium, vessels)
- Musculoskeletal (bone & tendons)
- Skin
- Islet cells (pancreas)

Neurological Determination of Death (Brain Death)

Neurological Determination of Death (NDD)

- Defined: the irreversible loss of the capacity for consciousness combined with the irreversible loss of all brainstem functions
- Patient's condition is irreversible - no hope for survival
- Absolute prerequisite to organ donation
- 2 physicians required to perform declarations

Brain Death

Brain death can be confusing, particularly for families who are confronted with the sudden death of someone they love because a brain dead person on a ventilator can feel warm to the touch and can look "alive."

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Brain Death

- The action of the brain swelling inside a closed space and the build-up of pressure is what can ultimately lead to brain death. As the brain swells inside the skull, it pushes downward toward the brain stem blocking all upward flow of blood. Depending on the type of injury, this may happen within minutes or over a period of days. Even while the heart is still beating and supplying blood to the rest of the body, blood that carries oxygen cannot reach the brain or the brain stem, which controls heart rate and breathing. The result is that the brain and the person dies

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Brain Death

Declaring someone brain dead involves no subjective or arbitrary judgments. Brain death is a clinical, measurable condition

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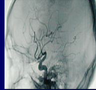
Clinical Testing for Declaration

- Oculocephic reflex
- Oculovestibular reflex
- Cranial nerve III
- Cranial nerves IX and X
- Apnea
- Or cerebral angiography
- Or isotope perfusion studies



NDD

"Severe Brain Injury to Neurological Determination of Death – Report & Recommendations", 2003

(Canadian Council for Donation and Transplantation)

Canadian consensus-based guidelines for the determination of brain death

Consent

Consent

- Consent is obtained from next-of-kin (even if potential donor has signed donor card)
- Family is approached only after NDD is understood and accepted.
- "Informed"

Assessment

Assessment

Rigorous process – includes;

- ABO/tissue typing
- Infectious disease testing
- Med-soc questionnaire
- Physical exam
- Organ/tissue specific assessment

Assessment

- Microbiology
  - Blood, sputum, urine cultures
- Hematology (q 4-6h)
  - CBC
- Coagulation (q 4-6h)
  - INR, PTT
- General Chemistry
  - Include liver, pancreatic, and cardiac profile

Assessment – Organ Specific

- **Kidney**
  - Urinalysis
  - Creatinine, Urea
- **Heart**
  - 12 lead ECG
  - Echocardiogram
  - Angiography if indicated

Liver
- Liver function tests

Assessment – Organ Specific

- Lungs
  - CXR q6h (measurements required)
  - Challenge gases q4h (to determine lung suitability)
  - Bronchoscopy
  - Bronchial aspirate for C&S and gram stain

Assessment – Medical Social History

- Provided by:
  - Knowledgeable historian(s)
    - Family member, 'significant other', friend, member of household
  - Current medical records
    - EMS, ER, Hospital, ME
      - Lab results, CXR, biopsies, cultures
  - Personal physician
  - Clinic records, if available
  - Physical exam

Donor Management

Donor Management

- The interval between brain death and the procurement of organs is most often characterized by unstable hemodynamic conditions. These conditions must be addressed and managed to maintain viability and optimal condition of the organs

Donor Management

- Hemodynamic maintenance
  - cardiovascular maintenance
  - Fluid replacement/maintenance
  - Inotropic support
- Electrolyte maintenance
- Ventilation maintenance
- Acid-Base maintenance
- Temperature maintenance
- Treatment of coagulopathies

Donor Management

"Medical Management to Optimize Donor Organ Potential – Report & Recommendations", 2004.
(Canadian Council for Donation and Transplantation)

Canadian consensus-based guidelines developed to establish best donor management practices in the ICU and the Operating Room to ensure optimal organ utilization.

Placement/Allocation

Organ placement / allocation

- National waitlist for all organs other than renal
- Regional sharing
- Provincial renal waitlists
- UNOS

Tissue Placement / Allocation

- Corneas are generally offered to surgeons in donor province – may be offered out if unable to place
- Musculoskeletal and cardiovascular tissue is generally processed and/or cryopreserved – shelf life = 5 years.

Organ Placement – Additional Considerations

- Flight availability
- Surgeon availability
- O.R. availability
- Recipient location
- Recipient status / compounding issues affecting transplant
- Ability to access requested/required diagnostic testing
- Tissue typing / virology times

Retrieval

Retrieval

- Proper retrieval, perfusion, and preservation is essential for optimal outcome of each organ and tissue recovered and transplanted

Retrieval

- Requires ultimate coordination
- Usually a set order for organ retrieval (heart, lungs, liver, pancreas, kidneys, bone, corneas)
- Incoming teams working again clock once aorta is cross clamped – even more evident if coming from distant program

O.R. plays a key role in the retrieval process

Retrieval

Time Restrictions from Cross-clamp

- Heart – 4–6 hours
- Lungs – 6–8 hours
- Liver – 12 hours
- Kidneys – 24 hours
- Pancreas – 8 hours
- Bowel – 4-6 hours

More Knowledge??

The need to improve procedures for identifying potential donors and approaching families of those at the end of life for the purposes of procurement of organs/tissue is frequently identified in the literature. Strategies suggested focus on need to increase knowledge based on the belief that knowledge will lead to higher levels of procurement.

Or Not??

However, there is increasing evidence that knowledge alone does not influence the willingness to engage in organ procurement and that attitudes may play a more important role.

Literature Scan...

- Studies reveal those more closely associated with the donation process may have a less positive perspective on donation.
- Physicians may experience a patient's death as a personal failure
- Nurses training often focuses on problem-solving – when someone dies, may have feelings of helplessness
- Studies also suggest nurses procuring organs may sometimes have a concern that they are violating their ethical responsibility of beneficence (do no harm)

"Trauma and Tribulation: the experiences & attitudes of operating room nurses working with organ donors"

- Working with organ donors in the Operating Room is highly stressful
- Concern for the donor and the family of the donor –(informed consent, disfigurement, fears donor may not be dead)
- These concerns are compounded by the fast pace and long surgical procedures leaving everyone emotionally drained.

Regehr, Kjerulf, Popova, & Baker, 2003

"Trauma & Tribulation....cont"

- Transplant teams frequently unknown which can result in technical problems (i.e., different names for instruments)
- "Converging on one patient"
- Compartmentalize tasks and avoid thinking of donor as whole person (allows for emotional distance)

What does this mean??

- The willingness of staff to participate in this vital aspect of health care may be compromised
- The attitudes of staff are likely to be transmitted to others (can potentially reduce willingness of staff to approach families of potential donors and present donation in a positive light)

What's Health Canada got to do with it?

Health Canada....

- Published proposed regulations to minimize potential health risks to Canadian recipients of cells, tissues, and organs (CTOs)
- Addresses safety in the processing and handling of these products
- Health Canada is the federal authority
- To date, there has been no consistent regulatory approach to maximize the safety of human CTO.

Regulatory Framework

- Regulations based on reports & recommendations from:
  - National Concensus Conference on the safety of tissues & organs (1995)
  - Krever Commission (1997)
  - Parliamentary Standing Committee (1999)
  - CCDT Tissue Committee recommendations (2002)

** Canadians insist on mandatory standards for CTO

Health Canada cont….

- Multiple sets of voluntary standards that vary in level of comprehensiveness are currently employed by CTO establishments.
- Contracted with Canadian Standards Association in 2000 to facilitate National Standards Publication

CSA

Z900.1

"Cells, Tissues and Organs for Transplantation and Assisted Reproduction: General Requirements"

- Five subset Standards:
- - Tissues for assisted reproduction
- - Tissues for transplantation
- - Perfusable organs for transplantation
- - Ocular tissues for transplantation
- - Lymphohemopoietic cells for transplantation

CSA

- Serves as a benchmark and provide minimum requirements for verification of safe practices
- Ongoing maintenance includes systematic review at least every 5 years & at any time amendments made be made by consensus process

Back to Health Canada.....

- While National Standards were being developed, Health Canada issued a directive: "Technical Requirements to Address the Safety of Human Cells, Tissues, and Organs for Transplantation.
- Provides guidance on donor screening, donor testing, CTO retrieval/collection, processing, preservation, packaging and labelling, storage, quarantine, record keeping, importation, distribution, transplantation, adverse reaction monitoring, and error and accident reporting, investigation and recall.

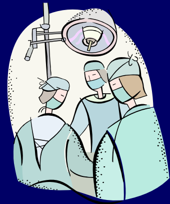
Health Canada

- CTOs which are not processed in accordance with the basic standards of safety will be considered by Health Canada to be "manufactured, prepared, preserved, packaged and stored under unsanitary conditions; to be adulterated; or to have the potential to cause injury under normal conditions of use."
- Summer 2007 – Regulations become law!!!!

What Does This Mean for the O.R.?

- Any organs/tissues transplanted should have documentation that will allow for tracking (complete all required forms!!!)
- Know where your O.R. orders bone/tissue from....is the source accredited and registered with HC?
- Does your O.R. package/culture/store tissue according to standards???

New clinical practices in Canada.....



Donation after Cardiocirculatory Death (DCD)

- Historically organ donation has occurred only after brain death.
- A very small percentage of all hospital deaths result in from the determination of brain death
- Reliance on donation after brain death severely limits the availability of organs for transplant

DCD

- Some people with non-survivable injuries to the brain never become brain dead because they retain some minor brain stem function. If such individuals made the decision to be donors or their families are interested, organ donation (donation after cardiocirculatory death) may be an option.

DCD

- The option of donating organs after cardiac death or "non-heart beating" donation may be presented to families after it is clear that their loved one cannot survive. Donation in such cases entails taking the patient off the ventilator, typically in the ICU. Once the patient's heart stops beating, the physician declares the patient dead and organs can be removed.

DCD

- Organ donation after cardiac death has been an end-of-life option for >30 years in the USA and Europe
- Canada's first case was in 2006 in Ontario– at least 10 cases have been performed to date.

Give the Gift of a New Beginning…

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