Canadian Perspective

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Differences

- No National OPTN or UNOS systems
  - Provincial programs (Gill AJT 2008;8:1580)
- National Standards for Perfusable Organs
  - Canadian Standards Association (www.csa.ca)
    - Initial distribution 2003 and updated 2007
  - Recent Health Canada Audit of all Live Donor programs
    - National Live Donor Paired Exchange Program

Living Donation Standards

- 13.1 Contraindications or Exclusion Criteria
  - 13.1.2 Examples
    - h) Persons at high risk for HIV, HBV or HCV*

• Mandatory standard for high risk
Source document: 1994 CDC criteria
Needs Updating and Risk Quantification

Exceptional Release

- 17.3 Exceptional release/distribution
  - 17.3.2 Based on clinical judgement of the transplanting physician with informed consent of the potential recipient.
  - 17.3.4 Requires authorization by the Medical Director and does not preclude usual practice described in SOP manual.
  - 17.3.6 A report documenting details of the exceptional release (reason, approval, follow up testing, etc)

Standard Screening of Live Donors

- 12.2.3 Assessment of Living Donors
  - 12.2.8 Tests specified in Clause 14.2 shall be performed within one month of surgery.
- 14.2.1 Infectious Disease Testing
  - 14.2.6.3 Minimum (serologic) testing includes HIV, HBV, HCV, and HTLV 1/11

Back to the Case

- The Canadian Regulations
  - Would not have prevented transmission
    - Serology within 1 month
  - But recipient and transplanting physicians would have been informed of increased risk
    - Extra precautions could then have been taken
      - NAT testing, donor counselling, recipient follow up etc.

Proposed recommendations NAT testing within 7 days
My Perspective

- Testing all live average risk donors Canada
  - Low prevalent HIV (0.2%) and HCV (0.8%) population
  - 450 average risk live donors yearly
  - Residual risk of about 1/45,000 by serology
  - Statistically miss 1 infection every 100 years
- Gain with NAT testing likely to be exceedingly small but very expensive

Proposed recommendations NAT testing within 7 days

- Testing increased risk live donors in Canada
  - Very few
  - Requires exceptional release report and recipient **consent**
  - NAT testing may not reduce residual risk of infection in increased risk donor to the level of serologic testing in average risk patients.
- Proposal seems reasonable but a challenge for some centers

Do we have a DTAC Equivalent?

Organ Transplantation Reporting of Errors/Accidents

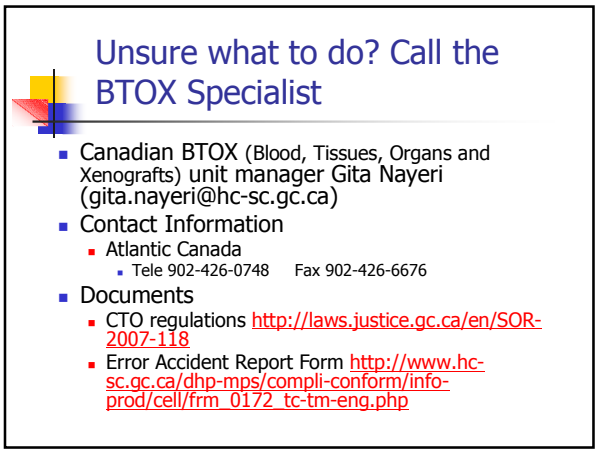
- Health Canada- Health Products and Food Branch Inspectorate
  - Established in 2007 to minimize potential risks of CTO (Cells Tissues and Organs).

Organ Transplantation Reporting of Errors/Accidents

- Error/Accident reporting
  - Error= deviation from a standard
  - Accident=unexpected event
- Required Actions Outlined
  - Report required with 24 hours with subsequent reports every 15 days until final report

Organ Transplantation Reporting of Adverse Reactions

- Health Canada- Marketed Health Products Directorate
  - Established in 2002 to enhance post market surveillance of drugs, biologics, and devices.
  - To date few reports of adverse events


Unsure what to do? Call the BTOX Specialist
Canadian BTOX (Blood, Tissues, Organs and Xenografts) unit manager Gita Nayeri (gita.nayeri@hc-sc.gc.ca)
Contact Information
Atlantic Canada
Tele 902-426-0748 Fax 902-426-6676
Documents
CTO regulations http://laws.justice.gc.ca/en/SOR-2007-118
Error Accident Report Form http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/cell/frm_0172_tc-tm-eng.php