The TTSN - A Collaborative Biovigilance System

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The Transplantation Transmission Sentinel Network
“That men do not learn very much from the lessons of history is the most important of all the lessons of history.”

Aldous Huxley (1894-1963)

http://www.directionjournal.com/vision/gauld.html
Related “Sentinel Events”

- **HIV transmissions - 1985**
  - Multiple organ and tissue donor
  - Lack of recognition that organ recipients infected by donor
  - **Lack of communication** - first recognized in 1991 in tissue recipient
  - Infectious disease testing deficiency (1st generation test HTLV-III Ab)
  - Tissue processing effectiveness and ineffectiveness realized
  - Voluntary reporting systems

- **HCV transmissions - 2000**
  - Multiple organ and tissue donor
  - Lack of recognition that organ & tissue recipients infected by donor
  - **Lack of communication** - first recognized in 2002 in tissue recipient
  - Infectious disease testing deficiency (HCV NAT not required)
  - Tissue processing effectiveness and ineffectiveness realized
  - Voluntary reporting systems
U.S.A.

- From one to 50, to more than 100 allografts, can be processed and distributed from one person’s tissue donation.
- One donor’s tissues can be recovered by more than one recovery entity and tissues from one donor can be sent to multiple tissue banks to process specific tissue types (skin, bone, soft tissue, cardiac, vessels, ocular).
- ≈ 13% of all tissue donors are organ donors, and
  ≈ 36% of all organ donors are tissue donors (ocular tissue donor data not included).
- Most recent estimate of MS tissue donations annually is 43,000 (FDA inspection blitz, 2005 activity).
Background of TTSN

- In June 2005, the Centers for Disease Control published a “Request For Application” (RFA) for federal funds for the development of a sentinel network for detecting emerging infections among allograft donors and recipients.
  - Driven by more transmissions via organ transplantation: Chagas, rabies, LCMV.....could these also be tissue donors?

- The United Network for Organ Sharing (UNOS), in an alliance with:
  - Association of Organ Procurement Organizations (AOPO);
  - American Association of Tissue Banks (AATB);
  - Eye Bank Association of America (EBAA);
  - American Society of Transplantation (AST); and
  - American Society of Transplant Surgeons (ASTS),

applied for and was awarded the cooperative agreement with the Centers for Disease Control and Prevention (CDC).
Background

- The TTSN is required to develop and maintain “a national sentinel network of organizations that recover, process, and distribute tissues from organ and tissue donors.”

- Additionally, a series of recommendations must be developed, “...based on network experiences and collaborative investigations with public health, to improve the safety of organ and tissue transplantation and identify emerging infectious diseases in organ and tissue transplant recipients. These recommendations will be made in concert with existing regulatory oversight agencies.”
Background

• In order to meet these requirements and to plan, direct and study the actions needed to accomplish these requirements, a TTSN Advisory Group was established.

• The TTSN Advisory Group includes representatives of the major stakeholder organizations representing organ and tissue procurement and use and regulatory agencies of the Federal government.
Stakeholders

The following organizations are represented:

- AATB - American Association of Tissue Banks
- EBAA - Eye Bank Association of America
- AOPO - Association of Organ Procurement Organizations
- ASTS - American Society of Transplant Surgeons
- AST - American Society of Transplantation
- STS - Society of Thoracic Surgeons
- AAO - American Academy of Ophthalmology
- AAOS - American Association of Orthopedic Surgeons
- AOSSM - American Orthopaedic Society for Sports Medicine
- FDA - Food and Drug Administration
- HRSA - Health Resources and Services Administration
- CMS - Centers for Medicare and Medicaid Services
- CDC - Centers for Disease Control and Prevention
- TJC - The Joint Commission on Accreditation of Healthcare Facilities

The AABB began to participate in the overall group in year two - developing Haemovigilance System
Background

- The primary tasks of the TTSN Advisory Group are to:

  - Develop a secure web-based electronic communication forum that will serve all groups involved in allograft transplantation
  
  - Improve information dissemination to clinicians, health professionals and patients
  
  - Develop a notification algorithm for trace-back and trace-forward allograft tracking to optimize collaboration between the clinical community and public health authorities
Background

• The TTSN may:
  - Allow for traceability of allografts (donor to recipients) using electronic methods that replace paper implant cards
  - Allow Eye Banks, Tissue Banks, and end users to generate reports detailing graft utilization
  - Allow Eye Banks and Tissue Banks to know the number of donors recovered nationwide
  - Provide an end user-driven mechanism for communication of adverse events
  - Provide a standardized mechanism for communication of potential or confirmed donor related disease transmissions among OPOs, Eye Banks and Tissue Banks
  - Improve patient safety
Background

- The TTSN will not:
  - Replace existing Eye Bank and Tissue Bank donor ID numbers
  - Replace existing adverse event reporting mechanisms
  - Require retroactive entry of donors
  - The system is currently only planned to track allografts that are used and will not be an inventory system for hospitals, Eye Banks, or Tissue Banks
TTSN System Description

• The web-based application has been divided into the following 5 stages of development:

  - Part A: Donor ID Registration (December 2006)
  - Part B: Graft Implant Registration (March 2007)
  - Part C: Adverse Reaction Registration (September 2007)
  - Part D: Regulatory and Public Health Notification (September 2008)
  - Part E: Community Education (September 2008)
Welcome to the TTSN Web site
Please login to get started

About TTSN
The Transplantation Transmission Sentinel Network (TTSN) was established by a CDC cooperative agreement in September 2005. The United Network for Organ Sharing (UNOS), in an alliance with Association of Organ Procurement Organizations (AOPO); American Association of Tissue Banks (AATB); Eye Bank Association of America (EBAA); American Society of Transplantation (AST); and American Society of Transplant Surgeons (ASTS), was awarded the cooperative agreement. The purpose of the Sentinel Network is to establish a network for detecting, communicating, and tracking allograft donors to recipients.

Important Links
AATB
CDC
EBAA
FDA
OPTN
The TTSN Pilot Project

- Practical flow & system software testing from May 2008 to August 2008
- Participating institutions represent stakeholders that will actively use system
  - 4 Organ Procurement Organizations
  - 8 Eye Banks
  - 4 Tissue Banks (Processors)
  - 4 Hospitals
- Identify areas needing improvement
- Use experiences for education at future implementation
TTSN System Review:
Site Map

Register Donor

Register Implant

Register Potential Serious Adverse Reaction

Register Investigation

Finalize notifications (if any)
“Vigilance is an attitude.”

Dr Luc Noel, WHO
July 2007, EUSTITE Meeting, V&S MAC
Thank you!