The Joint Commission's Current Thinking on Transfusion and Transplantation Safety

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- Who are we?
  - The Joint Commission is the nation's oldest and largest accrediting body.
  - 95% of patients admitted to a hospital today will enter a hospital accredited by the Joint Commission.
  - Accredit and evaluate over 15,000 healthcare organizations and programs in the United States.
  - The Joint Commission assesses compliance with standards during the on-site accreditation process.

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MMWR
Dispatch
July 1, 2004 / 53(Dispatch);1-3

Investigation of Rabies Infections in Organ Donor and Transplant Recipients ---- Alabama, Arkansas, Oklahoma, and Texas, 2004

On June 30, 2004, CDC confirmed diagnoses of rabies in three recipients of transplanted organs and in their common donor, who was found subsequently to have serologic evidence of rabies infection. The transplant recipients had encephalitis of unknown etiology after transplantation and subsequently died. Specimens were sent to CDC for diagnostic evaluation. This report provides a brief summary of the ongoing investigation and information on exposure risks and postexposure measures.

Organ Donor

The organ donor was an Arkansas man who visited two hospitals in Texas with severe mental status changes and a low-grade fever. Neurologic imaging indicated findings consistent with a subarachnoid hemorrhage, which expanded rapidly in the 48 hours after admission, leading to cerebral herniation and death. Donor eligibility screening and testing did not reveal any contraindications to transplantation, and the patient's family agreed to organ donation. Lungs, kidneys, and liver were recovered. No other organs or tissues were recovered from the donor, and the donor did not receive any blood products before death. The liver and kidneys were transplanted into three recipients on May 4 at a transplant center in Texas. The lungs were transplanted in an Alabama hospital into a patient who died of intraoperative complications.

Liver Recipient

The liver recipient was a man with end-stage liver disease. The patient did well immediately after transplantation and was discharged home on postoperative

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MMWR Weekly

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Brief Report: Investigation into Recalled Human Tissue for Transplantation --- United States, 2005--2006

On September 29, 2005, a human tissue-processing company discovered inaccuracies in donor records forwarded from a tissue-recovery firm and notified the Food and Drug Administration (FDA). An FDA investigation determined that the recovery firm, Biomedical Tissue Services, Ltd. (BTS) (Fort Lee, New Jersey), recovered tissues from human donors who might not have met donor eligibility requirements and who were not screened properly for certain infectious diseases. In October 2005, BTS and the five processors* that had received the tissues, working with FDA, issued a recall for all tissues recovered by BTS. The continuing FDA investigation determined that information for some donors (e.g., cause, place, or time of death) was not consistent with death certificate data obtained from the states where the deaths occurred. The investigation also determined that BTS had failed to recover tissues in a manner that would prevent contamination or cross-contamination and failed to control environmental conditions adequately during tissue recovery. These failures were violations of the Current Good Tissue Practice Rules† (effective May 25, 2005), which require manufacturers to recover, process, store, label, package, and distribute human cells, tissue, and cellular and tissue-based products (HCT/Ps) to prevent introduction, transmission, or spread of communicable diseases. In January 2006, FDA ordered BTS to cease manufacturing and to retain all HCT/Ps.

Current State: Transfusion and Transplantation

- **The potential for infections and other adverse outcomes in recipients is a significant quality and safety concern.**
- **Instances of infections and other adverse outcomes in recipients are well documented**
- **Adverse Event: Coordination and Communication**
- **Numbers of Transfusions and Transplantations are increasing**

What have we done lately?

- In July 2005, the Standards became applicable for Hospital including Critical Access Hospitals and Ambulatory Settings including Office-based Surgery

- Frequently Asked Questions (FAQs)

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Accreditation Process: Safety and Quality

- **Standards and Elements of Performance (Requirements)**
  - **General**
  - **Specific Requirements (Blood Transfusion Services and Donor Center; Tissue Storage and Issuance)**
- **Survey Process**
  - **Tracer Methodology**
- **Accreditation**
- **Office of Quality Monitoring**
  - **Complaints**
  - **Reviewable Sentinel Events**

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Standards and Elements of Performance

- They are the “what”
- Drive the Accreditation Decision
- Compliance versus Non-Compliance
- Evidence of Standard Compliance
  - Actions taken to bring the organization into compliance
  - Accreditation decision bases on the Evidence of Standards Compliance

Transfusion and Transplantation Standards and Elements of Performance

- **The standards are intended to help ensure that organizations have a well-coordinated system for managing blood they transfuse and tissues that they transplant/implant**
- **Currently, solid organs are not addressed**
- **Areas are common among both**
- **The differences are the specifics/details for some of these areas**

Common Areas

- 1. Responsibility for oversight
- 2. Standardized Procedures
  - Acquiring/Ordering
  - Receiving
  - Storing
  - Issuing

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Common Areas

- 3. Inspection of blood or tissue
- 4. Traceability from supplier to recipient or final disposition including documentation
  - Patient
  - Blood or Tissue
- 5. Documentation retention

Common Areas

- 6. Storage including back-up alarms
- 7. Acting as a supplier
- 8. Compatibility testing

Common Areas

- Adverse Events
  - Procedures to investigate
  - Bi-directional Investigation
  - Reporting
  - Identification of and notification to recipient
  - Quarantine/sequester

In Conclusion

- Requirements are separate, but address common areas
  - Similar issues
  - Similar problems
  - Similar concerns

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Joint Commission Future Plans

- Fall 2006: Standards Improvement Initiative
- Early 2007: Stakeholders Meeting
  - To explore identification of performance measure(s) for blood management
- Summer/ Fall 2007: Task Force
  - Review current Tissue Standards

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Questions?

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