Risk Managers' Focus Group:
Adverse Event Reporting Practices for Tissue and Cell Products
OMB Control # 0910-0497

Agenda
1. Welcome and Introductions, 10 minutes
2. Case Scenario One
3. Scenario 1 questions and discussion,
4. Case Scenario Two
5. Scenario 2 questions and discussion
6. General feedback; open discussion, 10 minutes
7. Wrap-up/concluding thoughts

Case Scenarios and Related Questions
The case scenarios are fictitious clinical vignettes. Each one describes an adverse event after implantation of an HCT/P. Although entirely fictitious, the scenarios are based on adverse event reports submitted to FDA.

Scenario 1:
Patient is a healthy 29 year old female s/p right knee arthroscopy with ACL reconstruction and implantation of anterior tibialis tendon allograft. Approximately 11 days post-op, the patient presented to the surgeon's office with complaints of swelling and redness around the joint. On exam the wound site is tender, surrounded by moderate erythema, and there is slight drainage of pus. The wound site was cultured and grew *Staphylococcus aureus*.

Scenario 1 Questions:

1. How would this case be reported within your facility (e.g., to infection control, risk management)? What additional information/assessments would be collected if risk management was involved?

2. Would the hospital report the case and if so, to whom (e.g., the vendor, FDA, other)? What factors does risk management use to assess if an event should be reported outside of the hospital?

3. Would it affect reporting if:

   the patient was re-hospitalized vs. only seen as an outpatient?

   returned to the OR for a second procedure?

   the clinician felt the tissue was not likely the cause of the infection?

4. Are there sources of automated data available at your facility, such as microbiologic culture results or ICD-9 coding, that could be used to actively screen for possible post-transplant infections?

Scenario 2:
A 46 year old male suffers a hip fracture from a fall. He undergoes a total hip replacement with implantation of cancellous chips. He also receives 3 units of blood during the procedure. Six months later he is found by his primary care physician to be HIV positive. The patient has no reported risk factors for HIV such as high-risk sexual activity, residence in an endemic area, or intravenous drug use.

Scenario 2 Questions

1. How does the organism in this case affect your decision on whether to report this event?

2. Describe your facility's protocols (pre-admission testing) that would serve as a baseline for post-operative evaluation. Which infections does your facility routinely detect by screening on admission and/or pre-operatively?

3. Are there other surveillance activities, in addition to reporting by the clinician involved, by which you might learn of either case 1 or case 2 at your facility? Are there data elements that you routinely collect or monitor from departments involved in tissue implantation (e.g., information on recipients, microbiological cultures, re-admissions)?

4. How are uses of tissue allografts tracked at your facility? Would this system be able to identify uses of human cells and tissues, such as corneas, tendon, skin, and bone transplants?

5. What are your facility's procedures for complying with Joint Commission and FDA requirements for reporting adverse events for tissue products?