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

PI: Craig E. Zinderman, MD, MPH; CBER/OBE/DE/TBSB
Sponsor: Robert P. Wise, MD, MPH; CBER/OBE/DE

Issue:
FDA and the Medical Device Safety Network (MedSun) would like to better understand how hospitals identify adverse events following use of human cells, tissues, and cellular and tissue-based products (HCT/Ps) and what factors influence hospital personnel to report or not report such events. In general, reports to FDA of adverse reactions following use of HCT/Ps have been fewer than anticipated. Because a risk manager's primary aim is to detect, evaluate, and prevent risks, we are interested in learning about the practices of risk managers and other multidisciplinary health care professionals in their facilities for managing the occurrence of infections in HCT/P recipients. To improve our understanding of this important issue, FDA's Center for Biologics and Research (CBER) and the MedSun contractor will convene a focus group of risk managers from several hospitals participating in the TissueNet Sub-network, MedSun's sub-network for HCT/Ps.

Background
FDA has received fewer than expected numbers of adverse reactions for HCT/Ps both from MedSun reporters and from tissue manufacturers since May 25, 2005, when new reporting regulations went into effect. MedSun Hospitals submitted only 40 tissue and cell related adverse event reports over a 2 year period from 2005 to 2007. Although the total number of tissue and cell procedures conducted at these hospitals is not known, these reports amount to less than 1 adverse event report per participating hospital. Further, only 14 of these events involved infections, with the remainder being product-related problems (e.g., dimensional complaints, packaging errors, product damage). If infections occurring after tissue implantation were routinely reported, and the general rate of surgical site infection is in the range of 2-5% of patients, one would expect more than 14 infections over 2 years at participating hospitals.

New FDA regulations requiring tissue establishments to report certain communicable disease-related adverse reactions went into effect in 2005. Over time, an increasing number of tissue products have fallen under this regulation (which applies only to tissues recovered after May 25, 2005), and a corresponding increase in the numbers of reported infections would have been expected. However, FDA has received 83 and 91 reports of infection following tissue use in 2006 and 2007. Although higher than the 20-21 reports per year submitted prior to the regulations (2001-2004,), this frequency is not as high as anticipated.

Several factors can influence a facility's particular reporting practices. First, post-surgical infections occur routinely in a small percent of patients and are usually unrelated to the tissue. Clinicians may only choose to report events to their local infection control specialists or other reporting mechanism when they have some reason to be alarmed or particularly suspicious of an allograft transmission, such as an uncommon (unexpected

in this context) infectious agent. Second, infections may be diagnosed in an outpatient setting such as Emergency Department or the surgeon's office, typically weeks after the implantation procedure, and will not necessarily require re-operation or hospitalization. Even if the patient is re-admitted, the event may not be reported through the same channels (i.e., Operating Room manager, infection control, risk management) as events that occur during a single stay. Other factors (litigation, explantation of the product, severity of outcome, etc.) may also influence the decision whether to report.

Objectives

- Understand practices for detecting, evaluating, and preventing tissue and cell product adverse events in their facilities.
- Understand practices that help to control and report HCT/P-related infections.
- Describe how the facilities investigate detected HCT/P infections. Identify the factors they examine and why. Understand factors used to assess whether detected infections may be caused by implanted tissues.
- Identify the types of adverse events that are likely or not likely to be reported, and why. Identify types of tissue most likely to be reported if involved in infectious events, if any.
- Identify any barriers to reporting adverse events for HCT/Ps.
- Assess awareness of FDA and Joint Commission requirements.

Methods

- Staffing
    - Facilitator: Tina Powell, Social and Scientific Systems, Inc. (SSS), FDA Contractor for the Medical Device Safety Network (MedSun), or other similarly qualified SSS staff member with focus group training and experience.
    - Other SSS participants: Carol Simmons, TissueNet Coordinator, Janet Camp.
    - CBER participants: Robert P. Wise, MD, MPH, OBE/DE, Acting Division Director; Craig E. Zinderman, MD, MPH, OBE/DE; Alexis Mosquera, OBE/DE; Laura St. Martin, OCTGT/DHT, Alan Ou, MD, MPH, OBE/DE, others TBD.

- Recruitment:
    - Other than FDA and contractor staff, no more than 10 individuals will participate in the focus group.
    - Focus group participants must be risk managers or other healthcare professionals, including infection control practitioners, healthcare providers, operating room managers, infection control practicioners or other hospital personnel without any restriction on sex or age. The potential pool will be recruited from hospitals registered in the MedSun

surveillance program sponsored by CDRH. Each participant will participate in one session lasting approximately 90 minutes.

Data Collection and confidentiality:

The data collected will be participant discussion in response to a series of case scenarios and questions (specific number depending on time and amount of the group's discussion) relating to the reporting of adverse events after tissue transplantations. The risk to participants is minimal as the work involves only voluntary discussion of non-sensitive topics regarding hospital reporting practices. The participants will not be required or asked to divulge any personal information. The contractor will recruit participants by contacting MedSun representatives at hospitals participating in the MedSun surveillance program and asking for volunteers. Participants will receive a gift with a dollar amount not to exceed $75.00 as an incentive for participating in the focus group.

The focus group will be conducted via telephone conference for 60 to 90 minutes. The contractor performing the focus group will ensure that the participants' identities and the identities of their institutions are not revealed to any FDA personnel. After the conclusion of the focus group, the contractor will prepare a narrative report summarizing the focus group results. The reports will include only de-identified data.