

**The University of Texas Southwestern Medical Center**

**Internal Audit Report 13:07  
Transplant Service Center**



**July 31, 2013**

Office of Internal Audit  
5323 Harry Hines Boulevard  
Dallas, Texas 75390-9017  
(214) 648-6106



**The University of Texas Southwestern Medical Center  
Internal Audit Report 13:07  
Transplant Service Center  
FY 2013**

---

**AUDIT REPORT  
July 31, 2013**

Daniel K. Podolsky, M.D., President  
The University of Texas Southwestern Medical Center  
5323 Harry Hines Boulevard, MC 9002  
Dallas, Texas 75390-9002

Dear Dr. Podolsky:

The University of Texas Southwestern Medical Center (Medical Center) Office of Internal Audit has completed its Transplant Services Center (TSC) audit as detailed below.

**Executive Summary**

Based on the procedures performed to evaluate 1) the adequacy of TSC policies and procedures; 2) TSC's response to external regulatory and accreditation audit recommendations; 3) donor inbound and outbound processing activities; 4) tissue inventory control; and 5) employee training, we found that TSC operates in a manner to promote effectiveness and efficiency with donor processing, staff training, and daily functions while maintaining general compliance with required federal regulations and accreditation standards.

Two key issues were noted as part of our review. First, The TSC has proudly experienced national recognition for its efforts in maintaining quality tissue for transplantation and continues to experience an increased demand for its services. The positive growth rate has created the need for further planning efforts to meet expanding space/storage requirements. Second, we could not find a documented charter, schedule or meeting minutes to help us determine the last time the Transplant Services Medical Advisory Committee had met. The Transplant Services Medical Advisory Committee focuses on external education and development initiatives.

These observations and recommendations are further discussed below:

Space Shortage

1. Due to increasing tissue recovery activity, the addition of new corneal processing techniques and reliance on tissue recovery procedures that are heavily manual and paper-driven, TSC space needs are strained. To address its current building space utilization issue, TSC had placed empty and necessary tissue distribution boxes as well as nitrogen tanks in areas that presented potential fire safety violations (first pointed out by the audit team and subsequently verified by an Environmental Health and Safety review on April 30, 2013). These violations were corrected by TSC Management but the remedies serve only as temporary solutions to TSC's space shortage issue. Thus, we recommend that TSC continue its efforts to prepare a cost benefits analysis that considers both the implementation of technology to manage its voluminous documentation requirements and physical space needs given growth of services provided to the community.

Further, TSC should be evaluated for consideration with the Institution's Archibus space management plans.

### Committee Review

The Transplant Services Medical Advisory Committee (the Committee) is a Medical Center standing committee appointed annually by the President. The Committee focuses on external education and development initiatives to support TSC. We did not find any evidence of a committee charter that outlines the committee's mission, composition, responsibilities and procedures for conducting business nor could we determine the last time the committee met. As this committee was formed at the direction of the Medical Center President as well as its importance to ensure governance and productivity of external relationships, we recommend that the purpose, objectives, memberships and meeting schedule be refreshed for active and effective meetings to occur.

TSC management has concurred with our recommendations and is currently in the process of finalizing a cost benefit analysis to address their technology and space shortage issues and evaluating key functions of their Advisory Committee. We appreciate and thank TSC staff for their assistance and support during this audit.

### **Detailed Results**

Individual results and recommendations are discussed below:

#### 1. Space Shortage

During our review of the operating structure, we noted TSC operations were stressed by the space capabilities of the Transplant Services Building. We found the following during our walkthrough of the facility:

- Empty and necessary tissue distribution boxes stacked the length and height on both sides of one hallway;
- Large nitrogen tanks were stored in the walkways of the laboratory; and
- Several non-storage rooms were filled to capacity with TSC supplies.

These issues represented fire safety concerns and were brought to the attention of UTSW's Environmental Health and Safety (EH&S) in April of 2013 to verify if those concerns presented potential violations of fire safety regulations. EH&S confirmed our concerns. The issues were immediately addressed by TSC management; however, the actions served only as a temporary remedy.

We discussed the space shortage issues with the TSC Director and were informed that at this point in time, TSC has the capability to operate without hindrance for at least the next year. However, it was the Director's belief that the TSC's continuously increasing tissue recovery activity and the addition of newly implemented cornea processing techniques would cause TSC to eventually restrict the amount of tissue they can recover, store and distribute. It was also brought to our attention that the TSC lab facilities had never undergone an expansion even though activities have steadily increased over time (65% donor recovery and 67% tissue distribution increase in the last nine years). The TSC is currently nationally recognized as a resource for tissue and a restriction in tissue recovery could jeopardize this status per TSC management.

Adding to space issues is TSC's intensive, manual paper-based procedures for tracking tissues from recovery thru distribution. All donor records are maintained for ten years, in line with external requirements. Records are stored at the TSC facilities for three years for quick access during external

assessments and then held in a storage facility off-site until retention requirements are met. Though we found access to and physical security of donor documentation well-controlled, the implementation of an approved information system will enhance TSC's donor information protection responsibilities further by 1) eliminating the voluminous paper charts currently taking up much needed space; 2) limiting access to donor/recipient information; 3) recording an audit trail for access to donor medical information; and 4) providing effective backup procedures of all donor and recipient information entrusted by the TSC to protect. TSC has recently begun and continues to evaluate electronic record systems specifically designed for its eye and tissue banking services.

As a result of this audit, discussions have occurred between TSC management and the Executive Vice President for Business Affairs to explore the future space needs of TSC.

#### Recommendation

The TSC Director should prepare a projection of costs that considers the expansion of operations, physical space needs, and implementation of technology necessary to meet future demands of its customer and markets. Cost projections should include, but not be limited to, estimates for additional equipment and staffing as well as the development or purchase of an information system designed specifically for eye and tissue banking management. The projected costs analysis should be reviewed by related Medical Center expertise (i.e., Financial Planning, Facilities Management, Information Resources, etc.) to ensure accuracy of potential costs and an appropriate means for funding. Finally, as the Institution is currently evaluating space via Archibus, the TSC Director should work with this team as well for its analysis.

The cost benefits analysis should be assessed by the Assistant to the President for formal presentation to Institutional Leadership for funding approval as appropriate.

#### Management Response

##### Implementation Status:

Management concurs with the Internal Audit Office's observations. A projection of costs will be developed for expansion of our current facilities and potential relocation to a facility more suitable to our needs. The cost projections will include estimates for necessary equipment and staffing requirements. Management will ensure that cost projections will be reviewed with proper individuals prior to presentation to Executive Management. Quotes have already been obtained for an electronic records system designed specifically for eye and tissue banks and this expense has been budgeted for FY2014.

##### Target Implementation Date:

January 1, 2014 (submission of initial cost projections)

##### Responsible Party:

TSC Director

## 2. Evaluate Transplant Services Center Medical Advisory Committee

The Transplant Services Committee is a President-appointed committee whose primary focus is on external education and development initiatives to support TSC activities. Despite its current position as a Medical Center standing committee, we were unable to find any documented meeting minutes, meeting schedules, or charter. We were also unable to verify the last time the Committee had formally met. However, it was noted that key members have had both group and individual interactions as needed through informal meetings with TSC management.

Recommendation

We recommend that the purpose, objectives, membership, and meeting schedule be refreshed for active and effective meetings to occur. TSC should collaborate with Committee membership and the Office of the President to develop and approve a formal charter. The following elements should be included in the charter:

- a. The committee's charge or mission statement;
- b. Authority and responsibility of the committee;
- c. Leadership and membership of the Committee; and
- d. Meeting schedule, activities and documentation of minutes.

Management Response

Implementation Status:

After discussion with the Assistant to the President, it has been determined that it is the Center's best interest to maintain the Tissue Transplant Services Center Medical Advisory Committee. Currently, development of a committee charter is in progress and establishment of committee meeting frequency and agenda is being discussed.

Target Implementation Date:  
September 1, 2013

Responsible Party:  
TSC Director

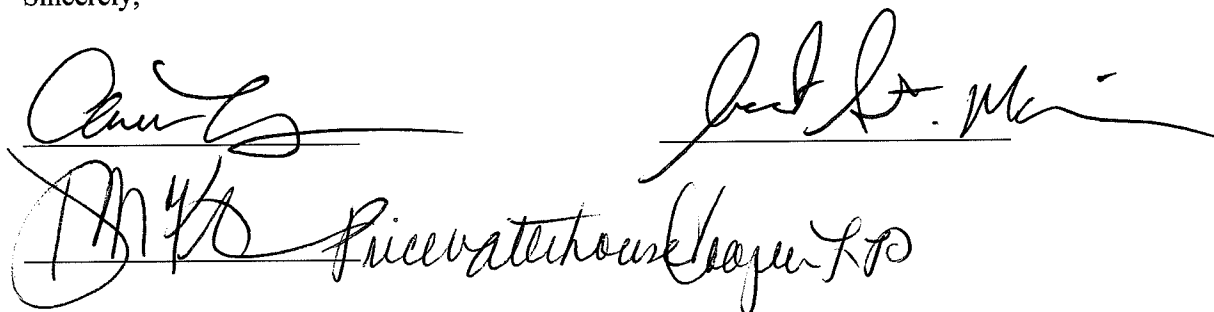
**Conclusion**

TSC has developed processes to promote compliance with external and internal regulations, efficient donor processing, effective staff training and functional daily operations. Recommendations include 1) addressing space shortage and 2) ensuring Transplant Services Medical Advisory Committee has its purpose, objectives, memberships, and meeting schedule refreshed for active and effective meetings to better enhance operations and governance. TSC management has concurred with our recommendations and its implementation is in process.

Jarrett Cocharo, CPA (on leave)  
Aaron Munoz, CPA, CIA, CGAP  
Scot St. Martin, CIA, CGAP, CRMA  
Debra McKibben

-Internal Auditor II  
-Senior Internal Auditor  
-Internal Audit Manager  
PricewaterhouseCoopers LLP

Sincerely,



## Appendix

### Background

The TSC provides services to hospitals and physicians primarily throughout North Texas and occasionally across the nation and world. It is a clinical and academic service center of the Medical Center which "completes the Circle of Care" from donation to transplantation by providing a full service tissue bank of tissue allografts. Transplantable tissues recovered and/or distributed by the TSC include corneas, sclera, skin, musculoskeletal and cardiovascular allografts. TSC is a national tissue resource for hospitals. It receives increased attention due to its association with the Medical Center and Parkland Hospital—particularly with Parkland's nationally recognized burn unit.

Our review of tissue inventory noted an increase over the past ten years. Donor recovery has gone from 473 donors in 2003 to 778 donors in 2012 (65% increase, one donor can contribute multiple tissues and with new techniques in corneal processing there is now an increased amount of tissue collection activity achieved from each cornea). Distribution of tissue has gone from 8,456 tissues distributed in 2003 to 14,116 in 2012 (67% increase).

Due to the high risk nature of services provided by the TSC, regulatory oversight is conducted by the Food and Drug Administration (FDA). Additionally, accreditation from two main agencies is required to conduct business: the American Association of Tissue Banks (AATB) and the Eye Bank Association of America (EBAA). FDA inspections and accreditation reviews are performed at a minimum of every three years by each agency. These inspections focus on communicable disease prevention, as well as, quality of tissue being used for patient needs. This high level of oversight and monitoring requires the TSC to develop and maintain an extensive quality assurance program which we found to be well structured.

### Audit Objectives

The primary objective of this audit was to provide reasonable assurance that the TSC has established operational controls that promote the proper environment for the following:

- Effectiveness and efficiency of operations and programs
  - Donor processing is managed in a way that safeguards donor and recipient information.
  - Tissue inventory is stored in a manner that prevents abnormal obsolescence and misidentification.
  - Employees are properly trained in a manner that fosters effective operations and safety.
  - Management of daily activities ensures the continued operation of the TSC as a nationally recognized source of quality tissue.
- Compliance with required federal regulations and accreditation standards
  - Documented policies and procedures create a proper operating and monitoring structure to ensure compliance.
  - External and internal review issues are addressed immediately and proper remedial action is taken.
  - Necessary information is communicated to proper individuals

### Scope and Methodology

Our fiscal year 2013 risk-based operational audit assessed the appropriateness of the TSC's established operational controls over donor processing, staff training, accreditation maintenance and daily operations. Our examination was conducted in accordance with guidelines set forth by the University of Texas System Policy 129 "Internal Audit Activities", the Regents Rules and Regulations and the Institute of Internal Auditors International Standards for the Professional Practice of Internal Auditing.

Procedures conducted to satisfy the audit objective included the following:

- Reviewed current documented policies and procedures of the TSC for compliance with FDA regulations as well as EBAA and AATB medical standards;
- Performed walkthroughs of donor processing, from initial contact with donor to distribution of recovered tissue;
- Tested donor processing information for compliance with FDA, AATB, EBAA and TSC requirements;
- Performed walkthrough of tissue inventory procedures;
- Tested tissue inventory for compliance with FDA, AATB, EBAA and TSC requirements;
- Reviewed maintenance and certification records of the TSC operating equipment and facilities;
- Tested equipment maintenance and certification records for compliance with FDA, AATB, EBAA and manufacturers' requirements;
- Reviewed space utilization of facilities and discussed disaster recovery planning;
- Reviewed training activities for staff;
- Obtained the most recent external review results from the FDA, AATB and EBAA and matched identified issues to TSC implemented and documented remedial action;
- Gained an understanding of reporting activities; and
- Gained an understanding of management's activities to promote efficiency of operations.

Final day of fieldwork for Transplant Services audit was May 16, 2013.