MEMORANDUM

TO: Deborah A. McGrew  
Vice President and Chief Operating Officer, UTMB Health System

FROM: Kimberly K. Hagara, CPA, CIA, CISA, CRMA  
Associate Vice President, Audit Services

DATE: October 15, 2013

SUBJECT: Ventricular Assist Device (VAD) Inventory Control Process  
Audit Control Number 2013-011

Attached is the final audit report regarding the VAD Inventory Control Process. This audit will be presented at the next Institutional Audit Committee meeting.

Additionally, please find attached Audit Services audit recommendation follow up policy. Each of the recommendations is classified by type at the end of its identifying number: Significant (S), Risk Mitigation (R), or Process Improvement (P). As you will note in the policy, the classification of the recommendation determines the frequency of our follow up. All follow up results are reported quarterly to the Institutional Audit Committee.

Thank you for your cooperation and assistance during the course of this review. If you have any questions or comments regarding the audit or the follow-up process, please feel free to contact me at (409) 747-3277.

Attachments

c: Donna K. Sollenberger  
Bernard E. Cherry  
Jaymee Mayo
The University of Texas Medical Branch
Audit Services

Audit Report
Ventricular Assist Device (VAD) Inventory Control Process
Audit Control Number 2013-011
October 2013

The University of Texas Medical Branch
Audit Services
301 University Boulevard, Suite 4.100
Galveston, Texas 77555-0150
Ventricular Assist Device (VAD) Inventory Control Process
Audit Control Number: 2013-011

Background
A ventricular assist device (VAD) is a mechanical pump used to support heart function and blood flow in people with weakened hearts. There are two basic VAD designs: transcutaneous and implantable. A “transcutaneous” VAD has its pump and power source located outside of the body. This type of VAD typically provides short-term support before or after surgery. An “implantable” VAD has its pump located inside of the body and its power source located outside of the body. Implantable VADs are primarily used for patients awaiting heart transplants or as a long-term solution for patients ineligible for heart transplants. VADs no longer needed by the patient may be “explanted” or removed.

During fiscal year (FY) 2012, the University of Texas Medical Branch (UTMB Health) performed 14 VAD implants and six VAD explants. During the current fiscal year through July 2013, 9 VAD’s were implanted and three were explanted. As of August 5, 2013, VAD-related expenditures totaled $797,185 with a majority of the expense (88%) related to the VAD pumps. In addition to ensuring these high-dollar items are safeguarded from theft or loss, individuals managing the inventory process must monitor equipment expiration dates.

Transplant Services and Nursing/Patient Care Services share the responsibility for managing VAD inventory. Both divisions administratively report to the Vice President and Chief Operating Officer, Health System.

Audit Objective
The primary objective of this audit is to ensure adequate controls are in place to acquire, store, track, monitor, and maintain appropriate levels of VAD inventory.

Scope of Work and Methodology
The scope of work included current inventory procedures and operations. Methodology included interviews, review of policies and procedures, and limited testing.

The audit was conducted in accordance with the International Standards for the Professional Practice of Internal Auditing as promulgated by the Institute of Internal Auditors.

Audit Results
Transplant Services and Nursing/Patient Care Services share the responsibility for managing VAD inventory. The key personnel involved and their respective responsibilities are as follows:

- **VAD Coordinator, Transplant Services** – Primarily responsible for coordinating the clinical aspects of care for the heart transplant and VAD teams; also responsible for VAD equipment inventory
- **Perfusionist, Nursing/Patient Care Services** – Primarily responsible for providing cardiac support for open-heart surgery patients on a 24-hour per day basis; also responsible for VAD equipment inventory
- **Senior Supply Coordinator, Nursing/Patient Care Services** – Manages the supply process to ensure availability of products and compliance with established rules, policies and procedures

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- **Coordinator Quality & Outcomes, Transplant Services** – Analyzes transplant department activities against quality measures, developing and implementing processes to improve performance
- **Administrative Director, Transplant Services** – Oversees the coordination, management and direction of VAD and Transplant services.

**VAD Program Equipment Management Protocol**
Audit Services reviewed the VAD Program Equipment Management Protocol and found the document thoroughly addresses the process for acquiring new or donated equipment, equipment recalls, and home equipment/readmissions to the hospital.

**Ordering/Receiving Equipment**
Audit Services review of the ordering, approval, and receiving processes for VAD equipment indicated appropriate segregation of duties and internal controls were in place and working as intended.

Additionally, Audit Services reviewed all fiscal year 2013 VAD purchase invoices noting devices were delivered to three different addresses on campus: “2nd Floor OR, Nurse Manager, 301 University Boulevard”; “301 University Boulevard” where the package is actually delivered to Materials Management at 14th & Strand; and, “14th & Strand”. The use of multiple addresses increases the risk of delayed notification to the VAD Coordinator and possible misappropriation. Additionally, device sterility may be compromised if handled incorrectly when received and processed.

**Recommendation 2013-011-01-R:**
The Administrative Director, Transplant Services, should ensure VAD equipment is consistently delivered directly to the Operating Room Suite in John Sealy Hospital.

**Management’s Response:**
It has been determined that all equipment should be delivered directly to the OR at the following address: **UTMB, Kim Yates, Nurse Manager, 2nd Floor OR, Room Mo23, 301 University Boulevard, Galveston, Texas 77555-0589**. Thoratec has been contacted via email to change the delivery address for UTMB VAD Services immediately.

**Implementation Date: 10/6/13**

**Audit Services Follow-up:**
Prior to issuance of the final report, Audit Services verified management implemented this recommendation.

**Inventory Management**
**Equipment Storage and Tracking**
Internal and external VAD devices/supplies are stored in separate secured locations to facilitate patient care. Additionally, device inventory is tracked separately with the VAD Coordinator.
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maintaining the tracking log for external devices/supplies and the Perfusionist maintaining the log for internal devices.

During the engagement, Transplant Services personnel indicated UTMB Health is in the process of purchasing a program management software system from the institution’s VAD vendor, Thoratec. The system, Thoratec Connect™, is expected to assist in centralizing and automating the current manual inventory management processes as well as enhance the patient care experience.

**Patient Donated Equipment**
Audit Services interviews with key VAD management personnel indicated UTMB Health currently accepts donations from patients of VAD related equipment and supplies that are no longer needed. The donated items are added to the VAD Coordinator’s inventory tracking log; however, the process for receiving items is informal and undocumented. Since there is a resale market for these items, the lack of appropriate controls for this process could present an opportunity for item diversion.

**Recommendation 2013-011-02-R:**
The Administrative Director, Transplant Services, should work with Health System leadership to determine whether to continue the practice of accepting equipment no longer needed by a patient. Should the practice continue, the Administrative Director should develop and implement documented controls to mitigate the risk of diversion.

**Management’s Response:**
Our practice has been updated to utilize returned equipment for inpatient, clinical and educational purposes. Returned equipment will no longer be allocated or charged to patients. The patient acknowledgement form has been updated to reflect this practice (see attachment).

**Implementation Date:** 10/1/13

**Audit Services Follow-up:**
Prior to issuance of the final report, Audit Services verified management implemented this recommendation.

**Inventory Testing**
Audit Services physically verified the 14 items listed on the perfusionist’s equipment log and the 75 items listed on the VAD coordinator’s log. Additionally, we selected a sample of 20 implants from FYs 2012 and 2013 and traced the devices to the associated documentation in each patient’s medical record. No exceptions were noted.

**Annual Maintenance Review**
The VAD Program Protocol indicates a maintenance review will be conducted annually and will include VAD Coordinator(s), and representatives from Clinical Equipment Services (CES). The CES Operations Manager stated all scheduled maintenance was performed in fiscal year 2013;
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however, no formal report was produced due to loss of staff. A new company, Sodexo, will assume clinical equipment management responsibilities effective September 1, 2013.

Recommendation 2013-011-03-R:
The Administrative Director, Transplant Services, should ensure incoming Sodexo personnel are aware of and comply with the requirement for an annual VAD maintenance review. Additionally, a written report supporting the review should be maintained for monitoring purposes.

Management’s Response:
The Administrative Director and VAD Coordinator met with David Peterson, Interim CES Manager on 9/23/14 to review VAD program equipment maintenance and tracking protocols. It was agreed that Sodexo will maintain this responsibility to include training and education of CES staff and provision of a written report verifying ongoing annual surveillance. CES expectations include: identification of staff members to be responsible for these activities and collaboration with Thoratec to ensure that CES staff are adequately trained in annual maintenance of VAD equipment and provision of the annual report to the Directors of VAD/Transplant and Patient Services.

Implementation Date: 10/31/13

Conclusion
Overall, adequate controls to acquire, store, track, monitor, and maintain appropriate levels of VAD inventory are in place and working as intended. Opportunities for improvement were identified in equipment deliveries, acceptance of donated equipment, and annual maintenance review.

We greatly appreciate the assistance provided by Transplant Services and Nursing/Patient Care Services staff and hope that the information presented in our report is beneficial.

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October 2013