UCI MEDICAL CENTER
LABOR AND DELIVERY
Report No. 2012-201

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Prepared by:
Jill Wilson
Senior Auditor

Reviewed by:
Gregory Moore
Audit Manager

Reviewed by:
Bent Nielsen
Director
GAIL DEVANEY
DIRECTOR, WOMEN AND CHILDREN'S SERVICES
NURSING ADMINISTRATION

RE: Labor and Delivery
    Report No. 2012-201

Internal Audit Services has completed the review of the Labor and Delivery and the final report is attached.

We extend our gratitude and appreciation to all personnel with whom we had contact while conducting our review. If you have any questions or require additional assistance, please do not hesitate to contact me.

Bent Nielsen
Director
UC Irvine Internal Audit Services

Attachment

C: Audit Committee
   Terry Belmont, Chief Executive Officer
   Karen Grimley, Chief Nursing Officer
   Alice Issai, Chief Operating Officer
Labor and Delivery  
Report No. 2012-201

I. BACKGROUND

University of California (UC), Irvine Medical Center is the only Regional Perinatal Center in Orange County and offers a full range of obstetric services which includes pre-pregnancy testing and planning through postpartum care. Specialized treatment is also available for high-risk pregnancies and babies born with medical conditions that require more intensive care. In addition, the Medical Center is committed to research and can offer patients the latest technologies, tests and treatments.

The Labor and Delivery (L&D) suites have an average of 120 deliveries per month. The Medical Center has large numbers of high risk obstetric patients because of the Newborn Intensive Care Unit (NICU). This Level III NICU is one of two in Orange County. Patients receive some of the best care in the region due to the emphasis on coordination of care throughout the maternity process.

II. PURPOSE, SCOPE AND OBJECTIVES

The purpose of the audit was to review internal controls, policy compliance, and information technology (IT) operations from July 2010 to present. Based on Internal Audit Services (IAS) risk assessment of L&D, the following objectives were established:

1. Discuss and review processes related to infant security including evaluating L&D access to ensure appropriateness;

2. Evaluate equipment and Clinical Engineering (CE) by sampling inventoried items to ensure correct tagging and location;

3. Review medication tracking and Pyxis system access and overrides;

4. Evaluate the following aspects of employee management: time clocking locations, overtime, vacation accruals and licensing for staff and registry;

5. Evaluate budget and accounting controls; and

6. Review selected IT operations.

III. CONCLUSION

In general, the selected L&D processes reviewed appear to be functioning as intended. However, business risks and control concerns were identified in medical
equipment inventory, medical equipment maintenance and tagging, business continuity and disaster recovery plans and user account management.

Observation detail and recommendations were discussed with management, who formulated action plans to address the issues. These details are presented below.

IV. OBSERVATIONS AND MANAGEMENT ACTION PLANS

1. Medical Equipment

   Background

   CE optimizes healthcare delivery through medical technology while ensuring that medical equipment used in clinical settings is effective and safe to use with patients, employees, and other individuals. At the Medical Center, CE operations are currently performed by an outside vendor, Philips Medical Systems (Philips).

   CE performs preventative maintenance (PM) inspections on medical equipment after the equipment is placed in service. Inspections should be scheduled in accordance with applicable regulatory (or other) guidelines. Inspections should be documented in the CE medical equipment database, and with tags that are attached to each medical equipment item.

   Observation

   IAS requested CE’s database equipment inventory report for L&D, Post Partum and the Newborn Nursery and noted the following:

   The CE inventory report did not agree with departmental equipment sampled by IAS. For the 22 items sampled, only 13 were located on the CE inventory report and only seven required PM tags. For the seven pieces of equipment observed by IAS, the dates on the PM tags did not agree with the dates documented in the CE medical equipment inventory report.

   The PM tags are necessary to show future inspection dates for medical equipment maintenance. A current date is needed to ensure CE knows when to perform electrical safety checks and preventative maintenance on medical equipment used in patient care.

   IAS also sampled equipment to ensure that the following tags were appropriate: Philips ID tags, Philips PM tags and Blue tags which identifies equipment that does not require preventative maintenance. For the 22 pieces of medical equipment tested on August 4, 2011 the following was observed:
• One of the 22 items sampled had an expired PM tag. The PM tag for the Envisor Ultrasound Machine (Phillips tag number 393182) had an expiration date of June 2011. Failure to obtain PM inspections in a timely manner may compromise patient care.

• Four of the 22 items sampled or 18 percent did not have blue tags. This includes two glucose handheld testers, one crash cart and one thermometer. As of the inventory date, it was unclear whether the Glucose testing equipment required a PM tag for ongoing preventive maintenance or a blue tag. Medical equipment should have either a PM tag or a blue tag.

• Four of the 22 items sampled or 18 percent did not have appropriate Philips ID tags. This includes two glucose handhelds (no Philips ID tags), thermometer (tag coming off) and a thermometer with two different Philips ID tags numbers (1148845 and 324532). Incomplete equipment inventory may result in an increased risk of loss of Medical Center equipment.

IAS also observed on two occasions where some of the nursing staff did not have a complete understanding of the CE PM and blue tagging system used on medical equipment. CE processes should be reviewed with the nursing staff to ensure a clear understanding of the medical equipment tagging and preventative maintenance procedures. Failure to ensure that all staff know the significance of the PM tags increases the risk of equipment being used on patients with inaccurate reading due to expired PM tags.

Management Action Plan

CE Response

We are currently in the process of updating our CE database (Infoview). Medical equipment inventory listings were recently sent to all departments’ for their review, inventory verification and to add any updates to their medical equipment inventory listing. As the inventory lists are returned to CE we will update the database as necessary and send an updated inventory list to the departments.

CE will implement a process that provides users (departments) the ability to access the new clinical equipment management system, Infoview. This access will allow department personnel to view their inventory lists, equipment inventory history, repair history, PM history, and submit online equipment maintenance requests. The last PM history in the Infoview system should agree with the current PM tags on the equipment. CE will provide in service user access training for the new Infoview system.
CE reviewed the PM history of the Ultrasound Machine number 393182 in the Infoview system, the system indicated that PM was completed on June 2, 2011. PM tag was replaced with a correct date.

CE reviewed the two ID tags on the thermometer with the number 1148845 and 324532, and the record showed that this is the same unit, serial number 4464515. CE removed tag number 1148845 from the unit and deleted the record of the number 1148845 from the Infoview database. The corrections were completed on September 23, 2011. CE will review the equipment items identified during the audit and make any corrections necessary to ensure the medical equipment is accurately tagged. CE will also continue to update the database to reflect the changes made to the medical equipment.

L&D Response

In September 2011, CE processes were reviewed with nurses during a staff meeting to ensure a clear understanding of the medical equipment tagging and preventative maintenance procedures. The nurses will ensure that equipment used on patients either has a current PM or a blue tag.

2. Business Continuity and Disaster Recovery Plans

Background

Business continuity and disaster recovery plans involve the identification, selection, implementation, testing, and updating of processes and specific actions necessary to prudently protect critical business processes from the effect of major system and network disruptions and ensure the timely restoration of business operations if significant disruptions occur.

Observation

During IAS interviews with L&D management we noted that documentation of business continuity and disaster recovery plans had not been completed, implemented and tested. IAS could also not determine if L&D has any service level agreements with the vendors of their Systems; specifically, HALO\(^1\) and Centricity Perinatal Clinical Information system\(^2\) to ensure continuity of critical services. Relevant considerations in this category include the following:

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\(^1\) Infant protection and monitoring system that uses unique skin-sensing Radio Frequency Identification (RFID) tags for easy and secure bypass of exits and also provides visual indication of the location of an infant.

\(^2\) The Centricity Perinatal Clinical Information System (formerly QS Perinatal) supports efficient documentation of mothers and infants throughout the perinatal care.
• Assess the criticality and sensitivity of computerized operations and identify supporting resources;

• Take steps to prevent and minimize potential damage and interruption, for example, information system backup and recovery procedures have been implemented, backing-up data, programs and software;

• Develop and document a comprehensive contingency plan, for example, assigns responsibilities for recovery, detailed instructions for restoring operations (both operating system and critical applications), etc; and

• Periodically test the contingency plan and adjust it as appropriate.

Management Action Plan

The Program Analyst in the Systems Application department will start creating a business continuity and disaster recovery plan sometime after October, 2011. In October, the new electronic medical record systems will be implemented so the information technology (IT) staff will be busy getting the new electronic record system up and running plus supporting its users. This will likely take weeks and once complete the Programmer Analyst can dedicate her time to the business continuity and disaster recovery plan. Estimated completion is March 2012.

3. User Account Management and Password Security

Background

User account management addresses requesting, establishing, issuing, suspending, modifying and closing user accounts and related user privileges with a set of user account management procedures. Also included is an approval procedure outlining the data or system owner granting the access privileges. These procedures should apply for all users, including administrators (privileged users) and internal and external users, for normal and emergency cases. Rights and obligations relative to access to enterprise systems and information should be contractually arranged for all types of users. Management should perform regular reviews of all accounts and related privileges.

Observations

User Account Management

A formally documented process to administer user accounts does not exist for L&D Systems; specifically, HALO and Centricity Perinatal Clinical Information system. However, an undocumented process exists where the managers
administering the systems specifically grant and revoke user access and privileges based on the job function.

A formal process should be developed for access requests to HALO and Centricity Perinatal systems. If possible, the process should follow an approval workflow where both the requestor’s supervisor and the application owner or custodians approve the request. Use of existing change and problem management systems, such as the Health Affairs Information Systems (HAIS) help desk system is recommended. In addition, a regular process of reviewing access should be documented; the review should validate that (1) existing accounts have a continued need for access and (2) the authorization level is appropriate.

Formalizing user account management will lead to better protection of IT systems and confidential data from unauthorized users.

**Password Security**

There is no policy to require and enforce periodic and regular password changes in the HALO Infant Security System. Potentially weak passwords that are not changed periodically may increase the risk of unauthorized access to the system. In addition, password complexity should adhere to UCI Medical Center standards.

The HALO system is not capable of enforcing regular password changes and complex passwords. HALO is not connected to the network, is limited to internal users and is located in secured areas which helps to decrease unauthorized access. In addition, L&D will remove HALO access, along with C-Cure access to the unit, once an employee separates. IAS recommends a manual process be implemented or at the very least a memo be distributed to encourage staff to change passwords periodically and to choose complex passwords.

**Management Action Plan**

**User Account Management**

An undocumented process exists for user account management where the managers administering the systems specifically grant and revoke user access and privileges based on the job function. A formal, documented process will be created to administer user accounts for L&D Systems; specifically, HALO and Centricity Perinatal Clinical Information system.
Password Security

HALO is a stand-alone system and is not capable of enforcing password changes. It would be too difficult to enforce password changes in a manual process. Management has reviewed IAS recommendations and will consider the recommendations during future reviews of this system.