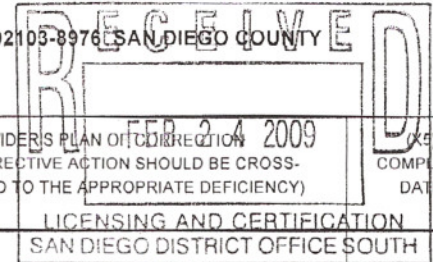


CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  050025	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  11/26/2008
NAME OF PROVIDER OR SUPPLIER <b>UNIVERSITY OF CALIFORNIA, SAN DIEGO MEDICAL CENTER</b>		STREET ADDRESS, CITY, STATE, ZIP CODE 200 WEST ARBOR DRIVE, SAN DIEGO, CA 92103-8976 SAN DIEGO COUNTY		
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	<p>AMENDED COPY</p> <p>The following reflects the findings of the California Department of Public Health during an entity reported incident investigation.</p> <p>Complaint Number: CA00163972</p> <p>Category: State Monitoring Sub-category: Retention of a foreign object in a patient</p> <p>Representing the Department: [REDACTED] HFEN</p> <p>The investigation did not represent the findings of a full inspection of the facility.</p> <p>Title 22 Nursing Services Policies and Procedures: 70213 (a) Written policies and procedures for patient care shall be developed, maintained and implemented by the nursing service.</p> <p>Based on interview and record review, the facility failed to ensure that an x-ray was taken at the completion of spine surgery for 1 patient in accordance with the facility policy and American Operating Room Nurses (AORN) recommended practice. As a result, a raytec (x-ray detectible surgical sponge) was left in Patient 1's spine surgery wound necessitating an additional surgery to remove the foreign body at a later date.</p> <p>Findings:</p>		<p>Upon discovery of the incident, the following actions were taken:</p> <ol style="list-style-type: none"> <li>1.) The involved OR nursing was counseled.</li> <li>2.) The Department Policy &amp; Procedure-Perioperative Services OR: Sponge, Needle and Instrument Counts was reviewed and revised to include: "An accurate surgical count is critical to ensure patient safety. No interruptions will be permitted during the count procedures. If an unpreventable interruption occurs, the count will be redone, and the physician notified of such action." (See ATTACHMENT A)</li> <li>3.) The OR staff was educated on the above change.</li> </ol> <p>Responsible Party: Director, Perioperative Services; Nurse Managers, Perioperative Services.</p> <p>Monitoring: To Ensure that no interruptions are encountered during counts, the process is being monitored and further actions are being taken as necessary.</p>	<p>09/19/08</p> <p>By 09/22/08</p> <p>By 09/22/08</p> <p>Began 11/12/08</p>



Event ID:0ELU11

2/19/2009

8:35:12AM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

*Brenda Quintana, RN* Asst. Director Regulatory Affairs/Administrative Services

2/23/2009

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	<p><b>Continued From page 1</b></p> <p>Patient 1 was admitted to the hospital on 6/19/08 with an admission diagnosis of lumbar stenosis (narrowing of the spaces in the spine resulting in compression of nerve roots) according to the Patient Demographic Data Sheet.</p> <p>A review of Patient 1's clinical record was conducted on 9/22/08 at 2:20 P.M. According to the clinical record, Patient 1 was taken to the operating room (OR) on 6/19/08 where a decompression lumbar laminectomy (removal of portions of bone from the lamina of the spine) and fusion (lumbar vertebrae are united together) of the 3rd, 4th, and 5th lumbar vertebrae was performed. An x-ray of the lumbar spine was taken at the beginning of the surgical procedure to confirm the location of the 3rd, 4th, and 5th vertebrae. No other x-ray was taken in the operating room on 6/19/08. Patient 1 was subsequently discharged home on 6/23/08.</p> <p>An interview was conducted with the Assistant Director of Administrative Services (AD) on 9/22/08 at 1:45 P.M. The AD stated that three months later Patient 1 was seen by [redacted] neurosurgeon, on 9/17/08, for a post-operative follow-up visit. The neurosurgeon ordered a lumbar spinal x-ray to be done. The lumbar spinal x-ray revealed a retained raytec sponge in Patient 1's lumbar spine area. The next day, on 9/18/08, Patient 1 was taken back to the OR. According to the operative report, Patient 1 underwent a "Surgical exploration of a previous lumbar instrumentation and removal of retained Ray-Tec sponge" at that time.</p>		<p><b>Continued From page 1</b></p> <p>Responsible Party: Director, Perioperative Services Nurse Managers, Perioperative Services</p> <p>At the time of the incident, the P&amp;P in place stated the following: "For all open spine and total joint cases (large joints), an instrument count is not required, however a post-op x-ray is taken after surgery in the OR when the first closing count begins. The film must be read by the Attending Physician, Radiologist, or Radiology Resident before the patient is discharged from the room."</p> <p>Education: All staff, including nurses and surgical technicians, were re-educated on the P&amp;P.</p> <p>Faculty, including the Department of Surgery and Department of Orthopaedics, were re-educated on the revised P&amp;P.</p> <p>Responsible Party: Nursing-Perioperative Services Director and Managers, Perioperative Services.</p>	<p>Began 11/12/08</p> <p>09/22/08 through 09/24/08</p> <p>09/24/08</p>

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	<p><b>Continued From page 2</b></p> <p>A review of the facility policy and procedure entitled "Sponge, Needle, &amp; Instrument Count" was reviewed on 9/22/08 at 2: 10 P.M. The policy indicates that "for all open spine and total joint cases, an instrument count is not required however a post-op film is taken after surgery."</p> <p>During an interview conducted with the AD, on 9/22/08 at 2:15 P.M., the AD acknowledged that the facility policy and procedure had not been followed. Patient 1 did not have a lumbar spine x-ray taken after <del>the</del> surgery on 6/19/08.</p> <p>An interview was conducted with the OR Registered Nurse (RN) Manager on 10/29/08 at 9:00 A.M. The RN OR Manager stated that x-rays may not have always been taken after spine cases in the OR. The OR RN Manager further acknowledged that the facility was not following their policy and procedure regarding taking an x-ray at the completion of spine surgery.</p> <p>An interview was conducted, on 10/29/08 at 9:55 A.M., with the circulating nurse assigned to Patient 1's procedure on 6/19/08. The circulating nurse stated that prior to this incident x-rays were "not very often taken" at the end of spine surgeries.</p> <p>An interview was conducted with Patient 1's neurosurgeon on 10/30/08 at 9:15 A.M. The neurosurgeon stated that he was not aware that it was the policy of the facility to take an x-ray at the end of all spine cases.</p>		<p><b>Continued From page 2</b></p> <p>Faculty-Perioperative Executive Committee; Department Chair, Surgery; and Department Chair, Orthopaedics.</p> <p>Monitoring: Daily review of post-operative x-ray films are conducted for all Spine and total Joint (large) cases and further actions are being taken as necessary.</p> <p>Responsible Party: Director, Perioperative Services and Nurse Managers, Perioperative Services.</p> <p>Members of the Medical Staff requested that the above P&amp;P be re-reviewed and provided their comments to the Perioperative Executive Committee. The decision to revise the P&amp;P included review of the following:</p> <ol style="list-style-type: none"> <li>1.) A review of Count P&amp;Ps from other UC Medical Centers and local hospitals.</li> <li>2.) A review of past surgical cases at UCSD Medical Center</li> <li>3.) A review of the AORN recommendations.</li> </ol> <p>The changes to the P&amp;P include the following: (See ATTACHMENT B) "Instruments should be counted</p>	<p>11/01/08 through 01/04/09</p> <p>12/10/08</p>

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	<p><b>Continued From page 3</b></p> <p>On 10/31/08 at 3:20 P.M., the AORN recommended practice entitled "Recommended practices for Sponge, Sharp, and Instrument Counts" was reviewed with the Director of Administrative Services. The recommended practice indicated that "Alternative measures should be established to minimize the risk of retained instruments during procedures in which accurately counting for instruments is not achievable (e.g. anterior-posterior spinal procedures). These measures should include the use of an intraoperative x-ray, read by a radiologist, before the patient is discharged from the OR."</p> <p>An exit conference was conducted on 11/26/08 with the Assistant Director of Administrative Services (AD) during which the AD was notified that an adverse penalty may be issued as a result of the facility failing to remove a sponge from Patient 1's spinal wound which necessitated in a second surgery to remove the sponge.</p>		<p><b>Continued From page 3</b></p> <p>on all procedures in which the likelihood exists that an instrument could be retained." (AORN- Perioperative Standards and Recommended Practices, page 296) For Spine and Orthopedic procedures, an instrument count is not mandated. According to the AORN standards, "Instrument counts may be deferred when there is no perceived risk of retained instruments." The Attending Surgeon (or his/her designee) may choose not to order an x-ray based on considerations such as incision size, fluoroscopy used during the case, and routine post-operative films. If an x-ray is ordered, it will be taken and read in the OR, before the patient is discharged to the Post Anesthesia Care Unit (PACU), A licensed physician (including, but not limited to Attending Surgeon, Surgical Resident, Radiologist, Radiology Resident) will read the film. Surgical Spine procedures may involve different approaches. Spine procedures utilizing a posterior approach will have the films taken at the discretion of the Attending Surgeon at the end of the procedure. Spine procedures that include an abdominal or thoracic approach,</p>	

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