

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

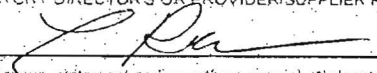
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050100	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 04/06/2009
NAME OF PROVIDER OR SUPPLIER SHARP MEMORIAL HOSPITAL		STREET ADDRESS, CITY, STATE, ZIP CODE 7901 FROST STREET, SAN DIEGO, CA 92123 SAN DIEGO COUNTY		
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	<p>The following reflects the findings of the California Department of Public Health during the investigation of an entity reported event.</p> <p>Event number: CA00176590</p> <p>Inspection does not represent the findings of a full inspection of the facility.</p> <p>Representing the California Department of Public Health</p> <p>Health and Safety Code 1280.1(c) For purposes of this section "immediate jeopardy" means a situation in which the licensee's noncompliance with one or more requirements of licensure has caused, or is likely to cause serious injury or death to the patient.</p> <p>Title 22 70225 (c) A registered nurse with training and experience in operating room techniques shall be responsible for the nursing care and nursing management of operating room service.</p> <p>Based on interview and record review, the facility failed to ensure that OR personnel accounted for all sponges used during Patient A's cardiac surgery prior to closure at the end of the procedure. As a result, the patient retained a sponge in the right pleural cavity that had to be removed during a second surgical procedure.</p>		<p>On February 2, 2009, Sharp Memorial Hospital (SMH) notified the California Department of Public Health (CDPH) a potential adverse event involving a retained sponge had been detected. On April 6, 2009, a telephonic exit conference was conducted between</p> <p>one deficiency based upon site visits (on 2/10/09 and 3/10/09) completed by the CDPH Health Facilities Evaluator Nurse. There was no Immediate Jeopardy declared in this case.</p> <p>The Plan of Correction is intended to service as this Organization's compliance with Title XXII regulation and should be deemed to be credible documentation evidencing correction of the deficiencies cited on the form 2567.</p>	

Event ID: 45EN11

4/7/2009

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	Continued From page 1 Findings: Patient A, a 69 year old female, was admitted to the facility on 1/29/09 for aortic valve (a heart valve) replacement and a coronary bypass graft x 3 (repair of three heart vessels) per the Operative Report, dated 1/29/09. According to the same report, the patient underwent the surgical procedure as scheduled. The surgery began at 8:28 A.M. and the patient was discharged from the operating room to the surgical intensive care unit (SICU) at 1:42 P.M., per the same record. At 6:04 P.M., the licensed nurse in the SICU documented in the Nursing Interdisciplinary Note, that Patient A was, "not doing well hemodynamically" (the patient was not able to sustain her blood pressure) and an x-ray was taken of the patient's chest. The x-ray showed that Patient A had cardiac tamponade and "a retained sponge in the right pleural space..." Cardiac tamponade is an emergency situation resulting from the presence of blood in the double walled sac that contains the heart, causing compression on the heart. As a result of the x-ray, Patient A was immediately returned to the OR for a second surgical procedure to repair the tamponade and to remove the retained surgical sponge.		To assure the Director of Surgical Services is responsible for the nursing care and nursing management of the operating room the following steps have been taken: 1. An Education and monitoring program has been implemented for all Operating Room personnel involved in Intra-operative counts. 2. All employees involved in the care of the affected patient during the operative procedure on 1/29/09 have reviewed the event with their supervisor and been coached/counseled on the correct procedure for Intra-operative counts and required documentation. To assure that all sponges are accounted for during operative procedure and to assure compliance with Policy and Procedure # 46708 Intra-operative Counts the following actions have been taken: 1. Re-education of all Surgical Services staff regarding policy and procedure # 46708 was completed via in-service. 2. An education module titled "Intra-Operative Counts" was developed and presented to all Surgical Services staff. 3. An Intra-operative count competency has been developed and will be completed by 100% Surgical Services staff that perform surgical count.	2/9/09 2/9/09 2/9/09 4/20/09
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	<p>Continued From page 2</p> <p>The OR manager was interviewed on 2/10/09 at 10:30 A.M. The OR manager explained that prior to the start of surgery, the first scrub and the second scrub assigned to the case, performed a count of all instruments and sponges to be used during the surgery. The count number was then entered on a white board in the OR and the fact that the count had been completed, was entered into the computer by the Circulating Nurse for the surgery.</p> <p>When the surgical procedure was completed, the practice at the facility was for three sponge counts to be performed before the patient's skin was closed. The counts were done by the first and second scrub personnel and entered into the computer as done by the Circulating Nurse. The white board, which had documentation of the actual number of sponges used during the surgery was cleaned at the end of the case.</p> <p>The OR manager said that the radiopaque sponges (sponges with a blue thread running through them that could be identified by x-ray) used in Patient A's surgery were packaged in bundles of 10 with 4 bundles to a packet. Each individual bundle was held together by a paper tape which was broken by the scrub technician when the count was performed at the beginning of the surgery.</p> <p>The procedure for counting the sponges was for the scrub technician to manually separate</p>		<p>To assure OR personnel perform the sponge count as directed by the policy and completely separate the sponges the following actions have been taken:</p> <p>1. As part of education, Surgical Technicians have been directed to completely separate the sponges during initial counts and subsequent counts when sponges are added to the sterile field.</p> <p>2. As part of education, the Circulating Nurses have been directed to assure the sponges are separated during all initial counts and subsequent counts when sponges are added to the sterile field.</p> <p>3. Competency validation for sponge counts for the Surgical Technicians and the Circulating Nurse will be documented in the Intra-operative Count competency.</p>	<p>2/9/09</p> <p>2/9/09</p> <p>4/20/09</p>

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	<p>Continued From page 3</p> <p>each sponge in a bundle and count it, observed by the second scrub, to ensure that the count was correct.</p> <p>At the end of the surgery, each sponge used during the procedure was placed in an individual clear pocket in a sponge counter bag. Each sponge counter bag held ten sponges. The counter bags were hung on an IV pole so that staff could visualize the number of sponges in each bag. As with the count performed prior to surgery, the count at the end of the procedure was verified by a second OR scrub person who observed the count. Documentation of the count was entered into the computer by the Circulating Nurse.</p> <p>The scrub technician (ST) assigned to the case was interviewed on 2/10/09 at 12:15 P.M. The ST recalled counting the sponges at the beginning and end of Patient A's surgery. The ST said that although he did not manually separate the sponges as completely as he should have, he was satisfied that the count was correct.</p> <p>RN 1, who was assigned as the Circulating Nurse for the case was interviewed on 2/10/09 at 12:30 P.M. RN 1 confirmed that she had been present in the OR when the sponge count was conducted at the start of the surgery and had written the number on the white board in the OR and had entered that the count was completed prior to surgery, in the computer.</p>		<p>To assure the circulating nurse documents the sponge count in the peri-operative nursing notes the following actions have been taken:</p> <ol style="list-style-type: none"> 1. As part of education, the Circulating Nurses have been directed to complete all required documentation for all counts in the peri-operative nursing notes. 2. Competency validation for documentation will be documented in the Intra-operative Count competency. <p>Monitoring Process:</p> <ul style="list-style-type: none"> • Completion of Education and Competency by 100% of assigned staff • Direct observation of 30 random surgical cases per month x 3 months • Staff not in compliance with Intra-operative counts policy will receive re-education including corrective action. <p>Responsible Party: Director, SMH Surgical Services Manager, SMH Surgical Services</p>	<p>2/9/09</p> <p>2/9/09</p> <p>5/7/09</p>

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	<p>Continued From page 4</p> <p>RN 2, who was assigned as the second scrub for Patient A's surgery, was interviewed on 3/4/09 at 11:10 A.M. RN 2 said that she had observed the ST counting sponges at the start of the surgery. RN 2 said the ST did not completely separate the sponges when he counted them. RN 2 said that she did not say anything to the ST about the way he was counting the sponges but she felt that the count was correct. RN 2 said that during the surgery, another packet of sponges was opened and she had counted those with the Circulating Nurse</p> <p>None of the three OR staff present at Patient A's surgery were able to account for the sponge found in Patient A's pleural cavity after the surgery on 1/29/09.</p> <p>Review of the Intraoperative Report for the first surgery showed that RN 1 had not completed the entry at the end of the surgery for the sponge count. The area on the report to confirm that the count was correct was left blank</p> <p>The facility policy and procedure entitled, "Intraoperative Counts" with a current effective date of 01/07, was reviewed. According to the policy, the RN Circulator was responsible for documenting the results of the intraoperative counts on the perioperative nursing notes. The number of correct closing counts performed should be documented. The policy further read that each item counted by the scrub person</p>			

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	Continued From page 5 must be separated for visibility. Patient A was admitted to the facility for cardiac surgery on 1/29/09. During the surgery, OR personnel failed to account for all the sponges used during the procedure. OR personnel did not perform the sponge count as directed in the policy when the sponges were not completely separated for the initial count. The Circulating Nurse failed to document that the sponge count was correct at the end of the surgery. As a result, a surgical sponge was left in Patient A's pleural cavity that required removal during a second surgical procedure.				

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