The following reflects the findings of the CALIFORNIA DEPARTMENT OF PUBLIC HEALTH during an Entity Reported Incident visit.

Entity Reported Incident number(s): #CA00136269.

Inspection is limited to the specific entity reported incident investigated and does not represent the findings of a full inspection of the facility.

Representing the California Department of Public Health: ________________________

T22 70223(b)(2) Surgical Service General Requirements

(b) A committee of the medical staff shall be assigned responsibility for:

(2) Development, maintenance and implementation of written policies and procedures in consultation with other appropriate health professionals and administration. Policies shall be approved by the governing body. Procedures shall be approved by the administration and medical staff where such is appropriate.

Based on clinical record review, policy and procedure review, and staff interview, the hospital failed to ensure that the Surgical Service nursing staff implemented the policy and procedure titled “Sponge and Sharp Count,” resulting in a surgical lap pad (sponge) being retained in Patient 2's abdominal cavity following surgery. Patient 2 had to undergo another surgical procedure to remove the sponge.

Preparation and/or execution of this Plan of Correction does not constitute admission or agreement by the provider of the truth of the facts alleged or conclusions set forth on the Statement of Deficiencies. This Plan of Correction is executed solely because it is required by Health and Safety Code Section 1280.

In January 2008, the Perioperative Services Department revised the sponge accounting procedure by implementing sponge counting bags. The accounting process was reviewed with staff multiple times at in-services and during shift huddles.

The process for counting additional items using a dry erase board in the operating suites was revised by placing permanent headings for sponge accounting on the boards to ensure consistency and accuracy. A dry erase board was designated exclusively for this accounting process in each OR suite.
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lap sponge, placing the patient at increased risk for complications due to the additional surgery and anesthesia.

THE FOLLOWING EVENT CONSTITUTED AN IMMEDIATE JEOPARDY (IJ), WHICH PUT THE HEALTH AND SAFETY OF SURGICAL PATIENTS AT RISK WHEN NURSING STAFF FAILED TO IMPLEMENT THE HOSPITAL'S WRITTEN POLICY AND PROCEDURE TITLED "SPONGE AND SHARP COUNT" AND IDENTIFY PRIOR TO SURGICAL CLOSURE THAT A LAP SPONGE WAS RETAINED IN THE PATIENT'S ABDOMEN. THIS FAILURE PLACED THE PATIENT AT RISK FOR INFECTION AND COMPLICATIONS FROM A SECOND SURGICAL PROCEDURE TO REMOVE THE LAP SPONGE.

Findings:

On 1/2/08 at 11:35 a.m., Patient 2's clinical record was reviewed and revealed that the patient presented to the Emergency Department on 12/8/07 by ambulance with a complaint of severe abdominal pain. Patient 2 was stabilized and admitted to the hospital for surgery for an acute abdomen. Patient 2 was taken to surgery on 12/9/07 and had an exploratory lap; small bowel resection with enteroenterostomy primary Paraventral abdominal wall hernia.

The patient was transferred from the post anesthesia care unit (PACU) to the critical care unit (CCU) on 12/9/07 at 2300.

The sponge accounting process was discussed at OR staff meetings on January 30, April 2 & 30, May 28, June 4, July 23, August 27, September 24, October 1, and November 19, 2008.

It was also a topic for discussion at the multidisciplinary OR Management Committee in January, February, March, April, June, September, and October 2008.

The policy and procedure was reviewed with staff in March 2008 and again after additional revisions in September 2008.

The Clinical Education Specialist, Peri-operative Services developed a competency tool to assess compliance with the new accounting process through self-assessment, direct observation, and a written test beginning on April 23, 2008 and ongoing.
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A review of the progress note dated 12/16/07, revealed documentation that the patient had a low-grade fever. The surgeon felt that the low grade fever was due to residual ischemic bowel or multiple other sources, such as DVT (Deep Vein Thrombosis) is a condition resulting from the formation of a blood clot (thrombus) inside a deep vein, commonly located in the calf or thigh. DVT occurs when the blood clot either partially or completely blocks the flow of blood in the vein) or drug toxicity. The surgeon did not feel at this time a Computed Tomography (CT) scan was indicated and continued antibiotic therapy.

Documentation indicated that on 12/15/07 at 9:20 p.m., the patient was transferred from the CCU to a Step-down unit (CSU). The patient continued to have minimal abdominal pain in the right lower quadrant. The patient had a limited upper GI study on 12/19/07 at 12:30 p.m., which indicated that the gastric bypass and what remained of the small intestines were intact with contrast flowing into the colon. However, there appeared to be a foreign body in the mid abdominal area. The surgeon ordered a CT scan, which confirmed lucency in this area consistent with a foreign body on 12/20/07 at 2:15 p.m. The results were called to the physician at that time.

A review of the progress note dated 12/20/07, indicated that there was a foreign body retained in the patient's abdominal area. Patient 2 returned to surgery on 12/20/07 at 6:50 p.m., eleven (11) days after the first surgery, and the surgeon removed the retained lap pad.

The Medical Staff Office offered a one hour CME for the medical staff on May 20, 2008 entitled: No Thing Left Behind: A Surgical Safety Project to Prevent Retained Surgical Items. This presentation was professionally videotaped and viewed by the OR staff at an in-service on June 4, 2008 with a follow-up visit by the presenter on October 1, 2008. The CD is available on the unit for review and for new staff orientation.

The Director and Clinical Education Specialist, Peri-operative Services conducted observational audits beginning July 21, 2008. Audit results indicated high compliance with opportunities for further improvement.

Since January 31, 2008 there have been no reports of incidents of retained sponges.
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On 1/2/08 at 12:45 p.m., RN A stated that she was the circulating nurse during Patient 2's surgery procedure. (A circulating nurse is responsible for patient safety during the surgical procedure. The circulating nurse coordinates care of the patient with the surgeon, scrub nurse/technician, and anesthesia provider. The circulating nurse also provides assistance to the surgical team throughout the surgical procedure). RN A stated that the laparotomy sponge (also referred to as a lap sponge or pad, is a 100% cotton cloth with a special weave and texture, designed for surgery) is banded. The lap pads are unbanded and laid out on the back table. The lap pads are counted by two (2) staff. The count is then documented on a board to ensure that there are only five (5) lap pads per band. The tally (count) is listed on the board. There is a middle count prior to the closure of the incision. The used lap pads are counted in fives. RN A stated that the scrub technician also counts the lap pads as they are being put into a plastic bag. The technician will say aloud, "I see five." In this surgical procedure four to five, packages of five (5) lap pads were used. RN A stated that she is sure that the process was followed.

On 1/2/08 at 1:25 p.m., Scrub Technician B (ST B) (scrub nurse/technician supports the surgeon by passing instruments during the operation while also maintaining patient safety) stated that the lap pads are counted pre-op by the scrub technician and the circulating nurse prior to the patient's arrival in the OR suite. ST B stated that only two (2) packs were opened and counted and the count as written on

The Clinical Education Specialist, Director of Peri-operative Services, or designee' will audit a total of 20 charts every month for two months in the Main OR, Outpatient Surgery, and Women’s Infants & Children’s to ensure compliance with the accounting process procedure. The need for ongoing audits will be evaluated based on the audit results.

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the white board. Other packs were opened as needed. ST B stated that she places the used lap pads in a bucket. ST B stated that this particular case was very bloody and the lap pads could have stuck together and this was not caught. It is easy to loose a lap pad when there is a lot of blood. Lap pads can stick together. It is up to the circulating nurse and the scrub technician to make sure that the count is correct before the patient leaves the OR suite.

The policy and procedure titled "Sponge and Sharp Counts," dated 3/2007, read under Procedure: A. Sponge Count: For the initial count, sponges will be counted once by the scrub and by the circulator before beginning any procedure. Initial counts provide a baseline for any subsequent counts. Subsequent sponge counts will be done: when sponges are added to the sterile field, before closure of any deep or large incision, immediately before completion of the surgical procedure, when each incision is closed, when permanent relief of scrub and/or circulator occurs. The count will be recorded on the OR count board to be visible by all OR team members.