CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050873	A. BUILDING _____ B. WING _____	12/10/2008

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
KAISER FOUND. HOSPITAL & REHAB. CENTER - VALLEJO	975 SERENO DR, VALLEJO, CA 94589 SOLANO COUNTY

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	The following reflects the findings of the CALIFORNIA DEPARTMENT OF PUBLIC HEALTH during an Entity Reported Incident visit. Representing the Department of Public Health: [redacted] HFEN. Inspection is limited to the specific entity reported incident investigated and does not represent the findings of a full inspection of the facility. INCIDENT/COMPLAINT CA00171025 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 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, Towel, Needle, and Instrument Counts," resulting in a surgical lap sponge being left in Patient 9's abdominal cavity following surgery.		Our medical center has taken this concern seriously and has investigated the event thoroughly in order to identify any opportunities to improve patient care and safety. **Immediate Actions Taken** 1. Implemented Standardized Pre-formatted White Boards to provide visual communication to further enhance the verbal handoffs within the surgical suites for all team members related to the case, including sponge, needle and instrument counts. 2. Implemented the use of the sponge pouch system to provide clear individual pouches to visualize each sponge individually during counts. 3. Training to prevent RFO's was presented at OR Staff Meetings . **Responsible Party:** OR Director **Implementation Date:** November, 2008	12/30/08 12/30/08 2/12/09 3/10/09

Event ID:5TF011 5/14/2009 2:38:16PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Karen Grunash TITLE: AAQS (X6) DATE: 5/29/09

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. Except for nursing homes, the findings above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

RECEIVED
JUN 03 2009
By

State-2567

6/3/09 3:50pm left message on Karen Grunash Voicemail POC accepted BVandley RN

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	Continued From page 1 THIS EVENT CONSTITUTED AN IMMEDIATE JEOPARDY (IJ), WHICH PUT THE HEALTH AND SAFETY OF PATIENT 9 AND ALL OTHER SURGICAL PATIENTS AT RISK WHEN THE SURGICAL STAFF FAILED TO IMPLEMENT THE HOSPITAL'S WRITTEN POLICY AND PROCEDURE FOR THE COUNTING OF SPONGES, WHICH RESULTED IN PATIENT 9 HAVING TO RETURN TO THE OPERATING ROOM A SECOND TIME FOR THE REMOVAL OF A RETAINED SPONGE. Findings: On 12/9/08 at 8 a.m., a review of Patient 9's record revealed that she presented to the Emergency Department with complaint of a continuous steadily increasing left sided abdominal pain (7/10; 10 being severe) and nausea on 11/7/08 at 1:20 p.m. Patient 9 was stabilized and admitted to the Surgical Department on 11/7/08 with abdominal pain with a small bowel obstruction. A review of the Operative Procedure Record dated 11/10/08, revealed that Patient 9 was taken to the operating room at 6:36 a.m. Patient 9 had an Exploratory Laparotomy (an exploration of the abdominal cavity) and lysis of adhesions (cutting away of scar tissue). Documentation revealed that the final closing sponge count was found to be correct. The Operative Report dated 11/10/08, revealed documentation that a midline incision was made		4. Revised and approved the Policy #2427 *Sponge, Towel, Needle and Instrument Count.* • Revised criteria of when sponge counts are to be performed: during initial setup, prior to closing a hollow organ, prior to closing a cavity, and prior to closing the skin. The skin count must be concluded before the completion of skin closure. • Criteria were established for when to do x-rays for abdominal, vaginal, and thoracic procedures: – There are discrepancies in the count prior to closure – There is an Emergency case when there is no count at the beginning of the surgery. – There is an unexpected change in the procedure. – There have been a large number of rapid successions of sponges placed in and out of the wound making accurate counting more difficult. – For abdominal, vaginal, and thoracic procedures when there are more than the usual hand offs in staff and providers during a procedure.	1/5/09, 2/2/09

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	Continued From page 2 through a previous scar. The fascia (the soft tissue component of the connective tissue) was then divided and the abdomen was entered. The adhesions were removed. The small bowel obstruction was resolved. Before closure of the abdominal incision, the surgeon placed Sepraflim (a protective barrier) on top of the omentum under the fascia. The fascia was closed using running #1 Maxon sutures. The skin was closed with staples and a dry dressing was applied to the incision. The documentation revealed that there were no complications during the procedure. Lap sponge count and instrument counts were correct. On 12/9/08 at 9:10 a.m., Staff V stated during an interview that less then five (5) Lap sponges were used to decrease the bleeding and oozing. Staff V stated that towards the end of the surgical case he flushed the abdominal cavity with one (1) liter or more of normal saline, while looking for any retained lap sponges (sterile absorbent gauze, which are used for the removing of excess fluid from the surgical site, for packing, or for tissue retraction. Radiopaque markers are incorporated into all sponges). Staff V stated that he tells the staff when it is time to close the abdominal cavity and he then asks for the "closing stitches." Staff is simultaneity counting the pads and instruments. Staff V stated before he closes the fascia, staff inform him if the "final" count was correct. Staff V stated that he got confirmation that the count was correct and he closed the skin with staples. Staff V stated that he discharged the patient on 11/20/08. The patient's pain level on a scale of 1 - 10 (10 being severe pain) was a 2-3 and the patient did not		• An addition was made to the Policy #2427 *Sponge, Towel, Needle and Instrument Count* regarding reduction of noise levels in the suites during counts. • A standard process/format was implemented which defines the required elements of the white board. Interim counts will be documented on the white board. Minimum required elements are sponges, sharps, miscellaneous and packed/tucked items. The sponge/miscellaneous "in and out" items will be announced and recorded on the white board **Responsible Party:** Executive Committee	

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	Continued From page 3 have any symptoms of an infection (temperature greater than 100o Fahrenheit). Staff V stated that the patient had an appointment with him on 12/1/08; however the patient cancelled that appointment and saw her primary physician (12/1/08) instead because she was not feeling well and had constipation. Staff V stated Patient 9's primary physician ordered an x-ray of her abdomen and the x-ray revealed a density (foreign body) in the left mid abdomen. A Computed tomography (CT) scan was completed and confirmed the finding. On 12/1/08, Patient 9 was admitted to the Surgical Department and on 12/2/08 Patient 9 underwent anesthesia /surgery a second time for an exploration for the removal of the retained laparotomy pad (Lap sponge) that was anchored to the kidney. A small portion of the patient's bowel was also removed due to infection caused by the lap sponge. Staff V stated that the sponge count was correct at the end of the second surgery. On 12/9/08 at 10:30 a.m., during an interview RN C stated Patient 9's Exploratory Laparotomy with lysis of adhesions on 11/10/08 started at 6:48 a.m. and she checked out at 7:15 a.m., which was 20 minutes into the case. RN C stated that the relief circulating RN came into the case at 7:10 a.m. RN C stated that when she set up for the case, she and the Surgical Scrub Technician (SST) count aloud the sponges together and then document the count on the white board at the back of the suite.		5. Implementation of the "Retained Foreign Object Playbook" which provides the necessary steps and tools to achieve success in preventing retained foreign objects. • Education regarding the RFO Playbook was provided by content expert and educator to the OR Staff **Responsible Party:** OR Director	2/12/09 3/10//09

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	Continued From page 4 RN C stated that the sponge count was done with the relief RN before she left the suite. RN C stated that the second count is not documented on the Operative Procedure Record, as this is not the practice of the hospital. In addition, RN C stated that the sponge count and the closing of a cavity are done simultaneously. On 12/9/08 at 11 a.m., SST J stated during an interview that she was the relief SST and had come into the case on 11/10/08 at 7:20 a.m., (approximately 30 minutes after the case had started). SST J stated that she and the relief RN counted aloud the sponges, needles, and instruments, before the first RN and SST left the case. The count was checked against the white board to double check the counts. SST J described how the counts are to be done. The count starts with the sterile field, Mayo stand, the back table, kick bucket, and the sponge holder in that order. When the surgeon starts suturing (closing of the abdominal cavity) and when the fascia is sutured closed, the surgeon will asked for Sepra Film. The RN and the SST start the sponge count and the process is the same as stated above. SST J stated that when they finished the sponge count, it was correct. SST J stated that she does not remember any clean sponges (not used) left on the sterile field. The surgeon could have reused a sponge after it had been counted to pack the cavity and forgot that the sponge was still in the abdominal cavity. SST J stated that the count could have been interrupted by the surgeon, if he had asked for something, but cannot remember that the count had been interrupted by the surgeon. If the count is		6. Specific Competency quizzes were completed by the OR staff regarding revisions to the Policy #2427 *Sponge, Towel, Needle and Instrument Count* to ensure that the OR staff understood the changes to the policy and the Playbook. **Responsible Party:** OR Director 7. Revised process for Sponge, Towel, Needle and Instrument Counts was added to the New Employee Orientation materials. **Responsible Party:** OR Director 8. Revisions in the Policy #2427 *Sponge, Towel, Needle and Instrument Count* were communicated to the surgeons and anesthesia staff. **Responsible Party:** Assistant Physician in Chief of Operating Room Assistant Chief of Anesthesia	2/12/09 to 5/30/09 4/20/09 3/2/09, 5/20/09

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	Continued From page 6 interrupted, the count is started over from the beginning. Upon inquiry regarding sponge count and suturing closed the cavity: SST J stated that this happens simultaneously. The surgeons do not wait to close a cavity while the sponge count is being completed. On 12/10/08 at 8:46 a.m., SST F stated during an interview that when the case is handed off to the relief SST and RN, the relief SST and RN count the sponges, needles, and instruments aloud together. The sponge count was correct for the case in question. SST F stated that she keeps a tidy field. SST F stated that she left around 7:30 a.m. and was not there to finish the case. On 12/10/08 at 9 a.m., RN G stated that the relief SST and she did the hand off sponge count aloud. RN G stated that she started with the sterile field, Mayo stand, back table, kick bucket, and the bags (used sponges that hang on a pole). It was a routine count and everything was counted for. The final count happens when the fascia is closed and is completed when the skin is stapled closed. RN G stated that even if the sponge count is done and correct, the surgeon can take a sponge off the field and reuse the sponge without telling the RN or SST. The count of the sponges is started at the same time the surgeon starts to suture close the fascia. There was no x-ray ordered, because in this case the sponge count was correct before the patient left the suite. The policy and procedure titled "Sponge, Towel, Needle, and Instrument Counts," dated 9/06 read		**Systemic actions** 1. Continuing Medical Education (CME) was provided to the surgeons and staff entitled *Highly Reliable Surgical Team (HRST)* including the elimination of Retained Foreign Objects. **Responsible Party:** Surgical Performance Improvement Committee Assistant Physician in Chief of Operating Room 2. Developed new surgeon orientation checklist which includes the sponge count process **Responsible Party:** OR Director **Monitoring Plan** 1. *Highly Reliable Surgical Team Report* process data for February 2009 – April 2009 reported compliance with the seven-step counting process.	3/10/09 5/18/09

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	Continued From page 6 "...Counts are done: c. Before any part of a cavity or cavity within a cavity is closed (i.e., C-section, uterus), d. When closure begins, e. Closure of skin (Count to be completed before skin is fully closed), f. All sponges used in the surgical field must be radio-opaque or x-ray detectable, g. Both the circulating RN and Scrub technician must account for every countable item at all times. Any item being retained inside the incision must be written on the white board. Notify the surgeon about the item before initialing the first closing count." The effect of this serious and systemic problem identified resulted in the failure of the facility to ensure that staff implemented the "Sponge, Towel, Needle, and Instrument Counts," policy and procedure, which resulted in Patient 9 having to return to the operating room a second time for the removal of a retained sponge. This failure put the health and safety of Patient 9 and all other surgical patients at risk for the potential of surgical complications.		2. Sponge count audits began in May 2009 at the conclusion of abdominal surgical procedures. A random sample of 30/month RFO audits will be completed. **Measure of Success** Three consecutive months of Retained Foreign Objects audit results at 100% compliance. Continue until there are 3 consecutive months at 100% compliance for all elements. Audit results are reported monthly to Medical Executive Committee until 100% compliance is met for 3 months, then reporting will occur quarterly. An evidence binder of supporting documentation is available onsite for review upon request.	

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