

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050076	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 02/25/2010
NAME OF PROVIDER OR SUPPLIER KAISER FOUNDATION HOSPITAL - SAN FRANCISCO		STREET ADDRESS, CITY, STATE, ZIP CODE 2425 GEARY BOULEVARD, SAN FRANCISCO, CA 94115 SAN FRANCISCO COUNTY		
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	<p>The following reflects the findings of the Department of Public Health during an inspection visit:</p> <p>Complaint Intake Number: CA00217978 - Substantiated</p> <p>Representing the Department of Public Health: Surveyor ID # 21155, HFEN</p> <p>The inspection was limited to the specific facility event investigated and does not represent the findings of a full inspection of the facility.</p> <p>Health and Safety Code Section 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>Abbreviations and Glossary:</p> <p>1) CC - Milliliter: a metric unit of volume equal to one thousandth of a liter.</p> <p>2) Cesarean Section - A surgical procedure in which incisions are made through a woman's abdomen and uterus to deliver her baby. Also called C-section, this procedure is performed whenever abnormal conditions complicate labor and vaginal delivery, threatening the life or health of the mother or the baby.</p> <p>3) Circulator or Circulating Nurse - Registered Nurse who is responsible for delivering quality</p>		<p>Title 22 70213 (a)</p> <p>Count Policy and procedure was revised to include completion of an X-ray prior to closure if the surgeon does not complete final sweep due to concerns for bleeding or other clinical considerations. Changes to the policy were reviewed at the Joint Practice Committee (JPC) with final approval by the Quality Utilization Executive Oversight Committee (QUEOC).</p> <p>Accountable Persons: Perioperative Services Clinical Service Director, & Perioperative Services Medical Director</p> <p>Perioperative staff were re-educated regarding the required elements of the count procedure, including use of the sponge holders.</p> <p>Accountable Persons: Perioperative Services Clinical Service Director, Chief Nursing Officer</p> <p>Extensive review of the event was conducted at the monthly OB/Gyn MD morbidity and mortality meeting. Surgeons were reminded of the importance of confirming accurate counts.</p>	<p>JPC March 3, 2010</p> <p>Final approval May 12, 2010</p> <p>April 4, 2010</p> <p>March 19, 2010</p>

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Justin M. Chalusch

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Sr. VP + CMA Mgr.

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7/22/2011

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	<p>Continued From page 1</p> <p>nursing care to the patient in the OR using the nursing process. This RN makes preparations for an operation and continually monitors the patient and staff during its course, who works in the OR outside the sterile field in which the operation takes place, and who records the progress of the operation, accounts for sponges, instruments, and specimens.</p> <p>4) Clot - The formation, development, or existence of a blood clot or thrombus within the vascular (blood vessel) system.</p> <p>5) Counter Bags (sponge holder bags) Transparent bags into which sponges are individually inserted by the circulating nurse, after they are counted.</p> <p>6) Embolization - A non-surgical, minimally invasive procedure performed by an interventional radiologist and interventional neuroradiologists. It involves the selective occlusion of blood vessels by purposely introducing emboli (something that travels through the bloodstream, lodges in a blood vessel and blocks it).</p> <p>7) Exploratory Laparotomy - Also "exploratory lap" or "ex lap". A surgical opening of the abdomen for exploration of body organs and tissue.</p> <p>Title 22 70213(a) Nursing Service Policies and</p>		<p>Accountable Persons: Chief of OB/Gyn Medical Director, Perioperative Services</p> <p>Questions related to individual performance were addressed via the appropriate confidential personnel processes.</p> <p>Monitoring: The Highly Reliable Surgical Team Committee continues to monitor the results of post-operative debriefing, including completion of count process.</p> <p>6 months of observational audits (5/month) will validate compliance with count process. Results of these audits will be reported to QUEOC (Quality Utilization Executive Oversight Committee).</p> <p>In addition, ongoing compliance monitoring will be reported through the quality oversight structure up to QUEOC.</p> <p>Accountable Persons: Perioperative Services Clinical Service Director, & Perioperative Services Medical Director</p>	

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	<p>Continued From page 2</p> <p>Procedures (a) Written policies and procedures for patient care shall be developed, maintained and implemented by the nursing service.</p> <p>This regulation was not met as evidenced by:</p> <p>Based on interview and record review, the hospital failed to implement their policy and procedure on counting surgical sponges when a laparotomy sponge was retained posterior to the uterus of Patient-1. The patient had a complex course that initially involved an emergent cesarean section then, a second surgery for an exploratory laparotomy due to excessive bleeding during her post operative course. Under an already compromised condition, Patient-1 had to undergo a third surgery to remove the retained sponge from the second surgery.</p> <p>Findings:</p> <p>Patient-1 was admitted to the hospital on [REDACTED]/10 for an emergency cesarean section that was done at 4:00 AM. Due to the emergent situation, initial and final counts of instruments and sponges were not done and this was documented by Surgeon-1 as follows: "Before using the (surgical)staples, an X-ray of the operative field was done. The X-ray showed no evidence of retained foreign body. The needles, instruments, and sponge count was not counted..."</p>			

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	<p>Continued From page 3</p> <p>According to the management team who consisted of the Operating Room Manager, Perioperative Services Director, Patient Safety/Risk Director, Interim Lead Service Director, and MCH Director during an interview on 01/19/11 at 10:16 AM, Surgeon-1's decision to override the standard instrument and sponge count procedure was a medical decision.</p> <p>On [REDACTED]/10 at 2:35 PM, Patient-1 had to undergo a second surgery due to a difficult postoperative course that was further complicated by intraabdominal bleeding and hypovolemic shock. In the second surgery, an exploratory laparotomy, 2000 cc's of clots and blood were evacuated. Surgeon-2 documented the following: " The patient tolerated the procedure well. Lap, sponge, and needle counts were correct times 2."</p> <p>After the second surgery, there was "concern for further bleeding, (and) the IR team called in for embolization. Bilaterally internal iliac embolization done, no complications. However, on imaging, retained lap sponge noted and plan now to take back to OR for ex-lap and removal of sponge".</p> <p>After a traumatic cesarean section followed by a complex postoperative course that required a second surgery to evacuate 2000 cc of blood and clots, Patient-1 was subjected to undergo her third surgery in less than 24 hours of delivering her baby. On [REDACTED]/10 at 11:15 PM,</p>			
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	<p>Continued From page 4</p> <p>Patient-1 underwent an exploratory laparotomy to remove the retained sponge. Surgeon-2 documented: "The abdomen was manually explored and the lap sponge was palpated posterior to the uterus and removed intact".</p> <p>In an interview on 01/19/11 at 10:16 AM, the hospital's management team who consisted of the Operating Room Manager, Perioperative Services Director, Patient Safety/Risk Director, Interim Lead Service Director, and MCH Director, stated their root cause analysis (RCA) revealed that the retained sponge occurred from the second surgery. Their investigation revealed that the X-ray from the first surgery definitely confirmed no retained objects. Therefore, their investigation lead them to conclude that the retention of the sponge was directly from the exploratory laparotomy from the second surgery.</p> <p>According to the management team, neither Surgeon-2 and Circulating Nurse-1 from the second operation were available for interviews with this surveyor. Surgeon-2 was on medical leave and Circulating Nurse-1 no longer was employed with the hospital. This surveyor requested that the facility contact Surgeon-2 to schedule an interview as soon as Surgeon-2 returns to work. The facility was also requested to provide this surveyor with contact information for Circulating-2.</p> <p>However, the management team did interview both Surgeon-2 and Circulating Nurse-1 during</p>			
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	<p>Continued From page 6</p> <p>The hospital's policy and procedure for sponge counting titled, "Count: Sponge, Sharp, Miscellaneous Small Item/Devices and Instruments", 16.19.01, review date: 12/08, revise date: 1/20/10 stated the following: "Purpose: To ensure that the patient is not injured as a result of a retained foreign body. To standardize the surgical count process. To account for instruments; reusable and disposable..." , "Procedure: Sponge Count (3.1.2): Sponge counts require the full attention of the scrub person and the RN circulator, (3.1.2.1)Sponges will be separated, counted audibly and concurrently viewed together during the count procedure...(3.1.2.2) Sponges will be counted in all procedures in which the possibility exists that a sponge could be retained. The RN circulator will record the sponge count on the count board as soon as possible, (3.1.2.3) The scrub person will observe the number of sponges added on the count board and acknowledge verbally that the written number and total are correct, (3.1.5)The RN circulator will contain and confine discarded, used sponges in designated sponge holder bags, (3.1.5.4)Final accounting of sponges by surgeon, circulator and scrub: Performed before the patient leaves the OR. Verify that all sponges (used and unused) are in the sponge holder bags. All sponge holder bags will be viewed separately."</p> <p>The hospital failed to follow their policy and</p>		<p>C.D.P.H. JUL 27 2011 L&C DIV DALY CITY</p>	

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	<p>Continued From page 7</p> <p>procedure for surgical sponge count when a sponge was retained in Patient-1 who was already compromised from two prior surgeries and had to undergo a third one all in less than 24 hours.</p> <p>This failure is a deficiency that has caused, or is likely to cause, serious injury or death to the patient, and therefore constitutes an immediate jeopardy within the meaning of Health and Safety Code section 1280.1.</p> <p>This facility failed to prevent the deficiency(ies) as described above that caused, or is likely to cause, serious injury or death to the patient, and therefore constitutes an immediate jeopardy within the meaning of Health and Safety Code Section 1280.1(c).</p>				

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