

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050222	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 01/22/2009
NAME OF PROVIDER OR SUPPLIER SHARP CHULA VISTA MEDICAL CENTER		STREET ADDRESS, CITY, STATE, ZIP CODE 751 MEDICAL CENTER COURT, CHULA VISTA, CA 91911 SAN DIEGO COUNTY		
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	<p>Continued From page 1</p> <p>size) during Patient 1's cardiac bypass surgery procedure (a surgical procedure to improve blood flow and oxygenation to the heart muscle). One bulldog clamp was not accounted for at the end of the patient's operation. Following the surgical operation, when an initial search did not produce the missing bulldog, and there were concerns about the ability to visualize it on the X-ray, there was no evidence that the facility intensified the search, even though the bulldog remained unaccounted for. The facility also failed to ensure that consistent, complete, and accurate verbal and written information was shared between departments pertaining to the unaccounted for bulldog clamp, in order to perform an accurate initial radiological search for the missing item. Ten days following his bypass surgery, Patient 1 required a second surgical operation to remove a retained foreign body from his chest cavity, which was then identified as the unaccounted for bulldog clamp.</p> <p>Findings:</p> <p>On 1/9/09 at 1:15 P.M., a record review was initiated. Per the admission History and Physical dated 12/15/08, Patient 1 was admitted to the hospital on 12/15/08 with diagnoses that included respiratory failure and pneumonia. His medical history was significant for hypertensive heart disease (heart disease related to high blood pressure) and diabetes. Per a cardiac surgery consult dated 12/19/08, Patient 1 had severe coronary artery disease (diseased blood vessels of the heart) and severe left ventricular dysfunction (a condition in which the left ventricle or chamber of</p>		<p>operating room when an incorrect/inconsistent count has been identified. Counts are written on the white board prior to the start of each case, during the case each item added is documented on the white board at the end of the case, the white board numbers must match the numbers on the field.</p> <p>If still unresolved, the RN Circulator notifies the surgeon of the need for an x-ray and an x-ray will be taken before the patient leaves the OR. Post-op safety for the patient will always be the first consideration.</p> <p>(B). Nurse Manager Surgical services (C). Random audits to ensure staff is following hospital policies.</p> <p><u>Process to follow when a foreign object is not found after an x-ray is performed.</u></p> <p>(A). If the radiologist has any questions about what he is looking for, he must contact the surgeon in the operating room. The surgeon or designee will personally describe the missing object, procedure performed, the exact area of the surgery (Right Lower Left abdominal or left upper chest etc.), and any other information that might be helpful. Policy will be</p>	4-30-09

Event ID:UTL511

5/14/2009

9:31:31AM

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	<p>Continued From page 2</p> <p>the heart did not function properly).</p> <p>Per the nursing Operating Room (OR) Record, dated 12/22/08, the patient underwent quintuple cardiac bypass (5 coronary arteries bypassed) surgery on 12/22/08. Per this same document, the surgical count was "unresolved" and an "X-ray was taken....and read by radiologist and cleared for pt (patient) to be transported to SICU (surgical intensive care unit)."</p> <p>A review of the physician progress notes dated 12/30/08 revealed that Patient 1 developed excess fluid around his lungs, and a chest CT scan (specialized X-ray) was performed.</p> <p>The chest CT scan result, dated 12/30/08, reported the following: "metallic foreign body in posterior pericardial fat consistent with retained foreign body."</p> <p>Per an Operative Report, dated 12/31/08, and 10 days following Patient 1's cardiac bypass surgery, he returned to the operating room where he underwent a second surgical operation for the removal of the "foreign body" from his chest cavity, which was identified as the unaccounted for bulldog clamp from the 12/22/08 cardiac bypass surgery.</p> <p>On 1/9/09 at 1:30 P.M., an interview was conducted with the OR Manager. The OR Manager stated that staff "did everything possible, but the heart was a thick muscle and it could be hard to see behind it even with an X-ray." Per the OR</p>		<p>changed to reflect new communication process.</p> <p>Radiologists educated about new communication process of calling the operating room if they are unable to locate/find foreign object and talking directly to surgeon or designee. If a radiologist is not available in-house, the films will be viewed remotely by an on-call radiologist and by the surgeon through our electronic system.</p> <p>Radiologists re-educated about availability of filters that may help in the possibility of identifying foreign objects.</p> <p>When the foreign object is not identified/visualized by the radiologist on the x-ray and not found by the surgical team, the surgery will be completed and the surgeon documents on his post operative note that the count was off and patient will have a CT scan whenever the patient is stable enough to have the procedure.</p> <p>(B). Nurse Manager Surgical Services</p> <p>(C). Review all unresolved foreign object for compliance with policy.</p>	

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	<p>Continued From page 3</p> <p>Manager, there were 2 scrub persons SP1 and SP2 (A nurse or technician who participates in a sterile surgical operation, prepares sterile supplies and passes them to the surgeon, assisting the surgeon during the procedure, accounting for needles, sharps, sponges and other supplies used during the operation) and 2 circulator nurses CN1 and CN2 (The circulator is responsible for managing the nursing care of the patient within the OR and coordinating the needs of the surgical team with other care providers necessary for completion of surgery) assigned to Patient 1's surgical procedure on 12/22/08.</p> <p>A review of the facility's policy and procedure entitled "Intraoperative Counts" was conducted on 1/9/09. Per the policy, "sponge, sharp, miscellaneous item and instrument counts were the dual responsibility of the scrub person and the RN (registered nurse) circulator with full accountability for the process. The policy documented that the RN Circulator and scrub person were to conduct a systematic and accurate accounting of all counted items in an effort to prevent patient injury from the retention of a foreign body. Per the policy, "relief counts" were to be done at the time of permanent relief of either the scrub person or the circulating RN, or both, to the extent possible, which included relief for meal breaks. In addition, the policy documented that "all disposable counted items shall be accounted for and disposed of during end-of-procedure cleanup per policy." If a surgical count was unresolved, and the patient's condition allowed, an X-ray was to be taken before the patient left the OR so that a radiologist could check for</p>		<p><u>Process for Requesting Radiography/Communication</u></p> <p>(A). The RN Circulator will enter a request for x-ray in the computer for potential foreign body retention specifying the name of the object and lists all areas to be x-rayed, e.g. where an incision was made and the risk of retention of a foreign body is possible. Once the request is enter in the computer system the RN will call the radiology department to expedite x-ray procedure and answer any questions. At Chula Vista, a separate x-ray will be taken of the type of item missing, if it is of an unusual description, (ie. not a needle), so that the Radiologist will be aware of what the item looks like under imaging.</p> <p>RN's & schedulers in radiology educated about new process. Policy approved by surgery supervisory committee. It is expected that a radiologist read films taken for the purpose of identifying a possible retained foreign body before the patient leaves the OR.</p> <p>(B). Nurse Manager Surgical Services and Manager Radiology Services</p> <p>(C). Audits to ensure compliance with new process.</p>	4-30-09	

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	<p>Continued From page 4</p> <p>potential foreign body retention.</p> <p>On 1/21/09 at 9:15 A.M., an interview was conducted with Patient 1's cardiac surgeon, Medical Doctor (MD) 1. MD 1 was told by the scrub and circulating staff in the room that the "count was off." According to MD 1, there was a discrepancy among the staff as to the actual number of bulldogs that were supposed to be accounted for. Circulator Nurses (CNs) 1 and 2, and Scrub Person (SP) 2 said that there were supposed to be 5 bulldog clamps, but SP 1 thought there were only supposed to be 4 bulldogs. SP 1 told MD 1 that he "gave him 4 bulldogs and got 4 back." MD 1 stated that, while he looked "several times" in the surgical wound for a retained bulldog and did not see one, he needed to be cautious when moving Patient 1's heart because of the patient's condition. MD 1 was told that the X-ray was "negative" (for a foreign body) by the anesthesiologist. MD 1 confirmed that even with an X-ray, some potentially retained items could be difficult to see due to the density of heart muscle.</p> <p>On 1/21/09 at 11:30 A.M., SP 1 was interviewed. Per SP 1, "2 bulldogs were brought to him" at the start of the procedure. SP 1 stated that he asked for 2 more (at different times) from the circulator nurses for a total of 4 bulldogs. SP 1 stated that he did not participate in the initial counting procedure which was done prior to a surgical incision in order to establish a baseline. He stated SP 2 and CN 2 did the initial count together. SP 1 stated he was "more concerned with his needle count because it was easier to lose a needle." SP</p>		<p><u>Education</u></p> <p>(A). The nurse and other circulating staff have been re-educated about the importance of ensuring accurate count when staff is relief for breaks. CN2 was re-educated about surgical count policy and procedure. All surgical staff were re-educated about surgical count policy and procedure, the importance of ensuring compliance with policy and procedure and any deviation from policy will result in corrective action up to and including termination. CN will ensure that counts are been done prior to surgery, during surgery and prior to cavity closure and suture. At the time of all relieves, items will be counted and accounted for on the surgical field and reported to the relieving tech. Additionally the information will be written and validated on the white board.</p> <p>(B). Nurse Manager Surgical Services and Manager Radiology Services</p> <p>(C). Random audits will be done to ensure that counts are being done per hospital policy and that radiology critical results are being</p>	4-30-09

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	<p>Continued From page 5</p> <p>1 also stated that he was relieved for a meal break during the surgical procedure. Per SP1, he did not conduct a "relief count" with the relief scrub person, per the hospital policy. He stated that would be "extremely difficult to do." Per SP 1 when he returned from his break, "they were doing a count and looking for 5 bulldogs." SP 1 stated that he had "4 bulldogs and got 4 back." Per SP 1, "We were not comfortable with the X-ray result because you couldn't see anything. I felt uneasy at the end of the case."</p> <p>On 1/21/09 at 12:10 P.M., CN 1 was interviewed. Per CN 1, the case was started with 3 bulldog clamps and 2 were added at some point during the procedure for a total of 5 bulldog clamps. Per CN 1, during the final counts when the bulldog could not be found, she told OR scheduler to "call for a STAT portable X-ray in the OR." CN 1 stated that she did not specify what the X-ray was for. CN 1 stated, "They usually know when you are asking for an X-ray like that what it's for." CN 1 stated she showed the X-ray technician what a bulldog looked like. Per CN 1, the anesthesiologist received a telephone report from the radiologist that the bulldog was not in the chest. CN 1 also stated that she was told the X-ray film result was of "poor quality."</p> <p>On 1/21/09 at 1:30 P.M. an interview was conducted with CN 2 who performed the initial baseline count with SP 2. Per CN 2, the case was started with 3 bulldog clamps and 2 were added at different times during the case, for a total of 5 bulldog clamps. CN 2 confirmed that during the</p>			

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	<p>Continued From page 6</p> <p>case, meal breaks were provided for all scrub and circulating personnel, but surgical counts were not performed at any of those times. CN 2 stated that SP1 told the surgeon, MD 1, that they were not missing a bulldog, but the circulating nurses told MD 1 that they were missing a bulldog. CN 2 stated that they were not sure how much of the bulldog was detectable via an X-ray, and when the X-ray film was viewed in the OR, "it was white and poor quality." CN 2 stated that she told the OR Manager that she "didn't feel comfortable" with the fact that the bulldog remained unaccounted for. Per CN 2, the OR Manager "didn't feel comfortable about it either."</p> <p>On 1/27/09 at 8:15 A.M., an interview was conducted with SP 2 who performed the initial baseline count of bulldogs with CN 2. SP 2 stated that she insisted to the surgeon, MD 1, that there was supposed to be 5 bulldogs accounted for. Per SP 2, when SP 1 told MD 1 that there were only supposed to be 4 bulldogs, that's when MD 1 "stopped looking." Per SP 2, the X-ray technician (XRT) came back into the room after the chest X-ray and said that the "radiologist could not find any bulldog." Per SP 2, "somebody" also called into the room and said there was "no bulldog on the film."</p> <p>A chest X-ray report, dictated by MD 2 (the radiologist who originally read the patient's X-ray as negative for a foreign body) and dated 12/22/08 at 1:11 P.M., revealed that the reason for the X-ray was "rule out retained bullnose retractor in chest." The report documented the following: "I see no</p>			

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	<p>Continued From page 7</p> <p>large radio opaque (visible by X-ray) foreign bodies to suggest a retained bulldnose retractor. Impression: Limited postoperative radiograph to evaluate for a retained bulldnose retractor. I see postoperative changes suggesting coronary artery bypass graft, however, there is no obvious foreign body seen."</p> <p>On 1/21/09 at 10:30 A.M., the chest film taken on 12/22/08 at 1:11 P.M., was reviewed with the Medical Director of Radiology (MDR). The MDR demonstrated how the bulldog clamp could be visualized on the film when certain "filters" were applied. However, per the MDR, it could "easily be confused with a mitral valve (a normal anatomical structure in the heart)." Per the MDR, MD 2 was told by the XRT to look for a "bulldnose retractor," which MD 2 thought was a larger chest retractor, rather than a small "bulldog clamp" device (a chest retractor for cardiac surgery is approximately 6 inches by 10-12 inches).</p> <p>On 1/21/09 at 10:50 A.M., the XRT was interviewed. The XRT was told by the OR nurse (unsure which nurse) to look for a "tiny piece of equipment called a bulldnose something, they showed it to me." Per the XRT he took the X-ray, it got processed and put in "synapse" (a computerized radiology system for remote viewing) for the radiologist on duty to view. The XRT did not know why the radiologist looked for a retractor. The XRT stated that he never had a discussion with the radiologist about what to look for. Per the XRT, the order from the OR for the chest X-ray was placed into the computer by Radiology Staff (RS) 1.</p>		

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<p>Continued From page 8</p> <p>The electronic chest X-ray order, dated 12/22/08, was reviewed with the XRT. The order contained the name of Patient 1, the admitting diagnoses of community acquired pneumonia, the requesting physician, and the OR location. There was no information in the order as to why the OR had requested the X-ray, or that the film needed to be reviewed for a retained foreign body/bulldog clamp. A section of the order entitled "comments" was left blank.</p> <p>On 1/22/09 an interview was conducted with the radiologist, MD 2. MD 2 was confident and firm in his recollection of the event. MD 2 stated that he was "offsite" on 12/22/08 and reviewed Patient 1's chest X-ray "remotely." MD 2 stated "someone from radiology, (2 possible names given, one was the XRT's) called me to view an intraoperative film to rule out a foreign body." Per MD 2, he called back to the facility and spoke with the XRT and told him that he needed to know exactly what to look for on the film. The XRT told MD 2 that they were looking for a "bullnose retractor." MD 2 stated, "I told the XRT, that I didn't see a bullnose retractor, and the XRT said he would tell them." Per MD 2, he had never heard of a bulldog clamp before, so he would have asked what it was, if he had been told that. "The XRT never described a clamp to me. I remember exactly what I said. I asked the XRT if I needed to call someone and he told me no, that he would take care of it." Per MD 2, he was looking for a large item and that is what he dictated in his report. MD 2 stated that he never called into the OR and talked with anyone about the missing</p>		

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	<p>Continued From page 9</p> <p>bulldog or to report the result.</p> <p>In an interview with the anesthesiologist on 1/21/09 at 8:50 A.M., he stated that on 12/22/08, "someone" from radiology called into the OR room and reported that "no foreign body" was seen on the chest X-ray. The anesthesiologist did not know who he received this report from. There was no documentation in the record by the anesthesiologist pertaining to this phone report.</p> <p>A review of the facility's policy entitled Critical Results Imaging Studies was conducted on 1/21/09. The policy defined a critical result as "initial diagnosis that represents a variance from normal to such an extent as to be life threatening or of sufficient acuity to warrant prompt medical or surgical intervention. Per the policy, an "imaging critical result" included a retained surgical foreign body. The policy established a timeline and defined the communication process that should occur between the radiologist and the patient's physician if an imaging result was positive for a critical result. However, the policy failed to provide any guidelines or outline a communication process that should occur if or when the radiologist was uncertain as to exactly what he/she was looking for when in search of a foreign body in an imaging study.</p> <p>Patient 1 had routine daily chest X-rays performed after his cardiac bypass surgery procedure, from 12/23/08-12/30/08. There was no indication documented on these daily X-ray reports which referenced the need to continue to search for a</p>			

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

TITLE

(X6) DATE

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.

050222

A. BUILDING

B. WING

01/22/2

PROVIDER OR SUPPLIER

STREET ADDRESS, CITY, STATE, ZIP CODE

CHULA VISTA MEDICAL CENTER

751 MEDICAL CENTER COURT, CHULA VISTA, CA 91911 SAN DIEGO COUNTY

SUMMARY STATEMENT OF DEFICIENCIES
(EACH DEFICIENCY MUST BE PRECEDED BY FULL
REGULATORY OR LSC IDENTIFYING INFORMATION)ID
PREFIX
TAGPROVIDER'S PLAN OF CORRECTION
(EACH CORRECTIVE ACTION SHOULD BE CROSS-
REFERENCED TO THE APPROPRIATE DEFICIENCY)**Continued From page 10**

potential foreign body/missing bulldog clamp. In addition, there was no documentation in any of the physician progress notes pertaining to a continued search or concern for a retained foreign body or bulldog clamp, until it was located as a result of the CT scan on 12/30/08.

The facility failed to implement its policy and procedure pertaining to surgical counts when the RN circulators and Scrub Persons failed to account for all disposable counted items at the end of Patient 1's surgical procedure; and therefore failed to prevent injury to Patient 1 from the retention of a foreign body, a bulldog clamp. In addition, RN circulators and Scrub Persons did not conduct surgical counts of items when meal breaks occurred during the patient's procedure in an effort to maintain communication about the status of surgical counts throughout the procedure. The facility failed to develop its policy and procedure pertaining to critical results imaging studies, which contributed to inconsistent and inaccurate communication and exchange of information between the OR and radiology departments pertaining to the initial radiological search for the missing bulldog clamp.

These violations resulted in injury and harm to Patient 1 when he required a second surgical operation to remove an unintentionally retained bulldog clamp from his chest cavity 10 days following his cardiac bypass surgical procedure.

On 1/21/09 at 3:30 P.M., the Vice President of Patient Care Services was informed of the potential

UTL511

5/14/2009

9:31:31AM

DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

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Continued From page 11

for an Adverse Penalty to be issued as a result of
these violations.

UTL511

5/14/2009

9:31:31AM

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

TITLE

(X6

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