

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050236	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 12/07/2011
NAME OF PROVIDER OR SUPPLIER SIMI VALLEY HOSPITAL & HEALTH CARE SERVICES			STREET ADDRESS, CITY, STATE, ZIP CODE 2975 Sycamore Dr, Simi Valley, CA 93065-1201 VENTURA 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: CA00284784 - Substantiated</p> <p>Representing the Department of Public Health: Surveyor ID # 13034, 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>DEFICIENCY CONSTITUTING IMMEDIATE JEOPARDY: T22 DIV 5 CH1-70223(b)(2) SURGICAL SERVICE GENERAL REQUIREMENTS</p> <p>(b) A committee of the medical staff shall be assigned responsibility for:</p> <p>(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</p>		<p>Simi Valley Hospital is committed to providing quality care. Preparation and/or implementation of this plan of correction does not constitute admissions or agreement by the provider of the truth of the facts alleged or conclusions set forth in the statement of deficiencies. The plan of correction is prepared and/or executed solely because it is required by law.</p> <p>The following actions and/or changes have been initiated in response to events cited for Patient A, and applies to all current and future patients admitted to the facility regarding the process to ensure accurate surgical instrument counts during surgical procedures.</p> <p>Sponge, Sharps, and Instrument handling policy and processes were reviewed, re-evaluated, and revised as follows:</p> <p>Existing policy "Care of Surgical Instruments" was amended and approved to include the identification of missing surgical instruments during the sterile processing tray reassembly period, with notification of the O.R. charge nurse of the discrepancy. Sterile Processing staff were educated on the policy and department's process changes by the Sterile Processing Supervisor. The Sterile Processing Supervisor or lead sterile processing technician will audit 100% of all reassembled surgical trays for both</p>	<p>10/27/11</p> <p>11/14/11</p>	

Event ID:IDQ711

5/24/2012

10:06:06AM

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

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(X6) DATE

Carlene [Signature] SRP 14 Care [Signature]

5/17/12

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	<p>Continued From page 1 appropriate.</p> <p>Based on staff interview, clinical record and facility policy and procedure review, the facility failed to implement its policy and procedures to ensure that instruments used during surgical procedures are accurately accounted for. Patient A had abdominal surgery on [REDACTED] 11. Following the surgery the patient complained of significant pain and experienced increased bile drainage (a fluid secreted from the liver). A series of abdominal x-rays performed on [REDACTED] 11, three days after the surgery, revealed a retained surgical instrument within the patient's peritoneal cavity. The patient returned to surgery on [REDACTED] 11 and a retained 8 inch Babcock clamp (a device used in surgery to grasp, join, compress, or support an organ, tissue, or vessel), found in the patient's abdomen, was removed. During the surgery, following the removal of the retained clamp, Patient A experienced sudden, swift bleeding from the area of the spleen, and an emergency splenectomy (removal of the spleen) was performed to control the patient's excessive bleeding. The facility's failure to ensure the instrument count was correct, and that no instrument was retained in Patient A following the surgery on [REDACTED] 11, created a situation that was likely to cause serious injury or death to the patient.</p> <p>Findings:</p>		<p>missing instruments and notification of the Surgery charge nurse for cases where an instrument cannot be located. Audits will be conducted daily for six consecutive months until 100% compliance is achieved, followed by monthly audits of 50 random cases for 6 six months with a goal of 100% compliance. Results to be reported monthly to the Interdisciplinary Patient Care Committee (quality assessment performance improvement committee) which reports up to Quality Council, Medical Executive Committee, and the Governing Board. All cases that fallout will be investigated by the Sterile Processing manager for investigation, process review, corrective actions and remedial 1:1 staff education as appropriate, in order to prevent future occurrence.</p> <p>All Operating Room staff were educated on the policy changes by the Director of Surgery.</p> <p>The Director of Surgery or Surgery Charge nurse will audit 100% of all surgical cases that require instrument trays for the presence of an inventory count sheet and for discrepancies in the documented inventory count versus the number of instruments in the actual tray. Any fallouts will be immediately reported to the Sterile Processing Manager for investigation and corrective action. Audits will be conducted daily for six consecutive months until 100% compliance is achieved, followed by monthly audits of 50 random cases for 6 six months with a goal of 100% compliance. Results to be reported monthly to the Interdisciplinary</p>	<p>06/30/13</p> <p>12/14/11</p> <p>06/30/13</p>

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9:37:04AM

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	<p>Continued From page 2</p> <p>Clinical record review on 9/29/11 beginning at 11:15 a.m. revealed that Patient A was admitted to the hospital on [REDACTED] 11 for scheduled abdominal surgery. According to the surgeons operative report the procedures performed included; attempted laparoscopic removal of a lap-band (a device placed on the stomach to reduce the size of the stomach), which converted to an exploratory abdominal laparotomy (opening the abdominal cavity) and removal of lap-band apparatus.</p> <p>According to the intraoperative nursing record dated [REDACTED] 11 Patient A entered the operating room (OR) at 7:40 a.m., and the procedure started (incision made) at 7:53 a.m. Per the anesthesia record documentation the incision was closed at 11:30 a.m. and the patient left the OR at 11:38 a.m. Surgeon 1 performed the procedure (laparoscopy, exploratory laparotomy and removal of lap- band) assisted by Surgeon 2. RN 1 (registered nurse) was assigned the responsibility for circulating nurse and completing the documentation on the intraoperative record. RN 2 was assigned as the scrub nurse for the procedure.</p> <p>According to the "counts verification" documentation on the intraoperative record RN1 completed an "initial" count and a "final" count with RN 2. Both counts were verified by RN1 as "correct." The "items" in the counts included "instruments, sharps, and sponges" and was "last modified" by RN 1 at 11:06 a.m.</p> <p>Post operative documentation states Patient A was noted to have "significant pain" and increased</p>		<p>Patient Care Committee (quality assessment performance improvement committee) which reports up to Quality Council, Medical Executive Committee, and the Governing Board.</p> <p>New facility policy "Prevention of Retained Surgical Items # B01163" created and approved as a companion policy to the existing corporate policy for Sponge, Sharps, and Instruments. Companion policy:</p> <ol style="list-style-type: none"> 1. Further defines countable items 2. Establishes a process for surgical instrument tracking to include amendment of existing tray forms. Each surgical tray form changed to include the name of the staff who prepared the tray, the staff who used and counted the instruments in that tray, and an inventory of items. Multiple trays of the same type are numbered in order to identify which tray was used, 3. Reinforces that all counts are performed in the same sequence for consistency 4. Reinforces that each count and count type will be documented in the medical record 5. Establishes criteria for a confirmation X-ray to be taken and read in the OR for open body cavity cases 	11/15/11

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	<p>Continued From page 3</p> <p>"bilious drainage" from the drain that was placed during the first abdominal surgery. Radiological studies done [REDACTED] 11 revealed "there is what appears to be a clamp or metallic forceps surgical device, which projected in the left upper quadrant of the abdomen and measure 23 cm (centimeters) in length." Physician's progress notes dated [REDACTED] 11, at 10 a.m. indicated the presence of a "retained instrument" in the patient's left upper quadrant.</p> <p>Patient A returned to the operating room on [REDACTED] 11, three days later, to remove the retained surgical instrument and to explore the origin of the bile leak. The second abdominal surgery was performed by Surgeon 3, assisted by Surgeon 2. According to operative report findings "a medium-sized Babcock clamp placed vertically in the left upper quadrant" was removed and sent to pathology. During the surgery, following the removal of the retained clamp, Patient A experienced sudden, swift bleeding from the area of the spleen, and an emergency splenectomy (removal of the spleen) was performed to control the patient's excessive bleeding. The post operative diagnosis included "status post exploratory laparotomy, removal of foreign body, retained surgical instrument. Splenectomy and placement of drain in the left upper quadrant on [REDACTED] 2011"</p> <p>A review of the facility's "System-wide Corporate policy No AD-14-005-S" "Facility Policy No B01135 - Sponge, Sharps, and Instrument Counts" (revised 7/09) on 9/29/11 revealed the policy summary/intent stated in part "...to provide guidelines for performing sponge, sharps and</p>		<p>where the depth of the procedure could result in the loss of an instrument.</p> <p>All Operating Room staff were educated to the new policy and processes by the Director of Surgery.</p> <p>All nursing and O.R. scrub technician staff receive an annual performance (competency) check for sponge, sharps, and instrument counts. These employees were retrained and participated in an interactive, hands-on count demonstration by the Director of Surgery. All new Operating Room employees will receive this training during clinical orientation on sponge, sharps and instruments count facility policies and be evaluated and validated for competency through direct observation by their assigned surgery preceptor before they are released to work without supervision.</p> <p>Interventional & Operative committee Physicians reviewed and approved Prevention of Retained Surgical Items B01163 policy and were educated to the event.</p> <p>Written education created by the Director of Surgery titled "Preventing Retained Surgical Items" was distributed via U.S. mail to surgeons who hold privileges at the facility.</p>	<p>12/14/11</p> <p>12/06/11</p> <p>01/11/12</p>

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	<p>Continued From page 4</p> <p>instrument counts in surgical procedures. Counts are performed to account for items and ensure that the patient is not injured as a result of a retained foreign body."</p> <p>The policy compliance key elements stated in part "Instruments must be counted on all procedures in which a major body cavity is opened, or the depth, or the location of the wound is such that any instrument could be retained". "C. Frequency of instrument counts. Instrument counts are performed at the following times: Initial-before the procedure to establish a baseline. Second-before wound closure begins;" "Additional counts: .3)."When a multiple stage operation is performed. 4) When additional instruments are added to the field, they are counted and the number is added to the count documentation."</p> <p>"Procedure: 1. Before surgery begins, the scrub person and circulating nurse count sponges, sharps and instruments together and out loud as each item is separated in the counting procedure." "2. This original count is recorded immediately after being taken by the scrub person and circulating nurse or physician." "3. All sponges sharps and instrument added to the operative field during surgery are counted together and out loud and recorded immediately by the circulating nurse." "4. During the operative procedure, the circulating nurse counts all sponges that are discarded from the operative field together and out loud with the scrub person etc." 5. Before closure of peritoneum begins the scrub person and the circulating nurse count together and out loud. All sponges/sharps/instruments contained within the</p>		<p>System wide corporate policy AD-14005-S, facility # B01135 "Sponge Sharps, and Instrument Counts" was revised by the Adventist Health Clinical Best Practices Committee with an advance copy provided to the facility on 11/10/11 for staff education. Final draft of policy received by facility, reviewed by medical Interventional & Operative committee, and was approved for use.</p> <p>Amended policy:</p> <ol style="list-style-type: none"> 1. Defines the neutral zone, minimally invasive surgery, and waived counts. 2. Additional sharps items that have a potential for retention were added. 3. Only towels with radiopaque markers will be used in wounds, counted, and easily distinguishable from other towels. Special order towels with radiopaque markers added to O.R. supplies. 4. Situational awareness (heightened awareness of distractions) defined to address scenarios vulnerable to surgical item retention. <p>All Operating Room staff were educated to the policy changes by the Director of Surgery.</p> <p>Electronic clinical documentation system enhancements were proposed to Adventist Health corporate Clinical Information System team and were approved. Computer fields added so that staff can now document the surgical count type and time it was performed.</p>	10/14/11 12/14/11

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	<p>Continued From page 5</p> <p>operative field which were counted before surgery and/or which were added during surgery. The circulating nurse records the tally on the count form and reports to the surgeon out loud, results of this count. 6. Before skin closure begins the scrub person and circulating nurse count out loud and together all instruments that were used after the peritoneum closure, plus all counted sharps and sponges. The final count, or correct/incorrect designation, is recorded by the circulating nurse.</p> <p>There was no documentation in the medical record to indicate when the "counts" were completed. In addition, there was no documentation to verify that the second count (to be done before closure of the perineum) was completed, as per facility policy.</p> <p>Interview with RN1 on 10/13/11 beginning at 1:45 p.m. verified that she was the assigned circulating nurse for Patient A's surgery on [REDACTED] 11, and was responsible for documenting that the sponge, sharps and instrument counts were correct. On 10/13/11, during an interview beginning at 3:05 p.m., RN 2 verified that he was assigned as the scrub nurse for the case. He stated that he brought the cart to the OR and opened the laparoscopic instruments etc., scrubbed, put the instruments out and counted the sponges, sharps (they go on the board) with circulating nurse (RN1). RN 2 indicated when the surgery converted "I told the circulating nurse (RN1) to open the Major lap tray and we did the count. Before the count I cleaned the Mayo stand and the back table from all the instruments for laparoscopy and put them aside. Then I put the Major tray on the table, removed the instruments</p>		<p>All Operating Room nursing staff were re-educated by the Director of Surgery on when to count and how to document count types and times using the existing electronic fields, as well as given education on the new electronic fields that were being created. Updated electronic fields were created by Adventist Health Clinical Information System team and were released for use by Adventist Health facilities. The Director of Surgery notified all nursing staff to begin using the new documentation feature.</p> <p>In order to monitor performance and ensure corrective actions have been achieved and sustained the Director of Surgery or the Surgery charge nurse will audit 100% of surgical cases each month to include:</p> <ol style="list-style-type: none"> 1. Direct observation of the surgical case to assess compliance with the Sponges, Sharps, and Instrument Count policy elements to include proper counting techniques performed by the circulating nurse and scrub tech, staff performed the correct number of counts at the correct times during the procedure, the surgeon(s) allowed time for all required counts, the surgeon(s) performed visual checks and wound sweeps of open cavity/organ cases, and the surgeon(s) verified that the final counts were correct. 2. Compliance with using surgical tray tracking forms to include signature of staff who assembled the tray, tray number, if applicable, signature of O.R. staff who performed the 	<p>12/14/11</p> <p>01/16/12</p>

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	<p>Continued From page 6</p> <p>and counted. I say the name of the instrument and the quantity and the other nurse puts check marks next to the numbers on the list and says "OK."</p> <p>During the aforementioned interview, the Director of Preoperative Services, who was present stated, "We are changing some of the procedures, and documentation process for the instrument count. The format of the instrument count list has been revised to include a space for the time each count is completed. We also are in the process of revising the binder/list of instruments that's kept in the OR." When asked if the check list for completing/verifying instrument counts used during the case on [REDACTED] 11 were kept/saved, the Director of Surgical center stated, "No, after all counts are verified the lists are discarded."</p> <p>On 10/25/11 during a telephone interview beginning at 1:15 p.m., the Sterile Processing Supervisor (SPS) was asked; if during the preparing/packaging the instrument trays, they discovered that an instrument is missing (based on the list) would they inform the OR? The SPS responded, "We usually do, but I don't think it was done for this case. In an interview with the Risk Management and Accreditation Director on 10/27/11 at 1:45 p.m. she stated " I know the policies in effect at the time of the incident, did not include for processing staff to call the OR if an instrument was missing from a tray. But we added it to the policy after the incident as part of revisions/ changes we made."</p> <p>Patients in whom a surgical instrument is left after abdominal surgery are at high risk for serious</p>		<p>count, documentation of the item inventory, report of any discrepancies in the inventory count with the number of instruments actually received.</p> <p>3. Medical record review for compliance that the correct number of counts and the correct type and frequency of counts were performed and documented.</p> <p>Audits will be conducted by the Director of Surgery or the Surgery Charge nurse daily for six consecutive months until 100% compliance is achieved, followed by monthly audits of 50 random cases for 6 six months with a goal of 100% compliance. Results to be reported monthly to the Interdisciplinary Patient Care Committee (quality assessment performance improvement committee) which reports up to Quality Council, Medical Executive Committee, and the Governing Board.</p> <p>All cases that fallout will be presented to the involved employee(s) by the Director of Surgery for investigation, process review, corrective actions, and remedial 1:1 education and competency reassessment in order to prevent future occurrence. The Director of Surgery will report physician fallouts to the Director of Medical Staff Office and the Chief of Surgery for peer review, intervention and corrective actions.</p>	06/30/2013

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	Continued From page 7 complications including pain, perforation, and infection. The facility's failure to ensure that the instrument count was correct and that no instruments were retained in Patient A following surgery on [REDACTED] 11, created a situation that was 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). 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).			

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