

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050348	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 07/22/2010
NAME OF PROVIDER OR SUPPLIER UNIVERSITY OF CALIFORNIA IRVINE MEDICAL CENTER		STREET ADDRESS, CITY, STATE, ZIP CODE 101 THE CITY DRIVE SOUTH, ORANGE, CA 92868 ORANGE COUNTY		
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	<p>Continued From page 2</p> <p>the "Time-Out" with other counts. Placement and removal of items should be noted on the Operating Room Record under "Nursing Notes."</p> <p>Letter F, stated if a count was unresolved, the RN (Registered Nurse) Circulator would notify the Surgeon and a thorough search of the operative field, back table, and the unsterile field would be initiated. In the event that the missing item was not located, the surgeon would order an x-ray to be taken and read prior to the patient being transported from the Operating Room.</p> <p>Letter K stated additional counts were to be completed in the following circumstances: a) addition of more countable items to the field; b) more than one incision and/or procedures on the same patient; c) before any cavity within a cavity was to be closed; d) before closure of the abdominal or thoracic cavity; e) when there was a change of the final member of the original team; and f) any time a member of the team requested a count. Another complete count of all sponges, instruments, sharps and small items should be performed at the time of permanent relief by the oncoming RN Circulator and Scrub Technician.</p> <p>The hospital's P&P on Surgical/Procedural Verification stated that verification of the correct person, correct site, and correct procedure would occur: a) at the time the procedure was scheduled; b) at the time of preadmission testing and assessment; c) at the time of entry into the procedure room; and d) anytime responsibility for care of the patient was transferred to another</p>		<p>POLICY REVISION</p> <p>The hospital's Policy & Procedure on "Counts-Sponge, Sharp, Instrument and Small Items" was immediately revised to require a mandatory x-ray on all open abdominal, thoracic and spinal procedures which last greater than eight hours OR when two or more surgical services perform consecutive procedures in the same body cavity.</p> <p>The policy further required a full field image or images be obtained. If a retained item is not seen on the x-ray by the Attending Surgeon, then the surgeon or his/her designee (with an appropriate scope of practice) will contact the Radiology resident and ask for a review of the image(s). The Radiology resident will notify the surgeon if a retained item is visualized so it may be removed. If the resident does not see a retained item, an Attending Radiologist will review the image(s) and confirm there are no retained items per radiological exam. The circulating RN will document who read the x-ray and the outcome in the OR record.</p>	2011 JUL 12 AM

Event ID: IU0F11

2/10/2011

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	Continued From page 2		<p>Page 3A (continuation of Page 3)</p> <p>A list of newly credentialed faculty surgeons is sent monthly to the Perioperative Educator. The Perioperative Educator sends an email communication to the surgeon(s) summarizing the "Counts" policy. The email contains a "link" to the hospital's policy website which will enable the surgeon to have access to the entire policy. The email is tagged with a "return receipt" to ensure the Educator is able to validate the surgeon has received the email. Any emails without "return receipts" will be followed up by the Educator.</p> <p>New residents/fellows are educated on the OR Counts policy upon arrival at the Medical Center. An email is sent to all incoming residents/fellows which summarizes the "Counts" policy. The email contains a "link" to the hospital's policy website which will enable the resident/fellow to have access to the entire policy.</p> <p>3rd and 4th year medical students are oriented to the OR and the "Counts" policy during their formal OR orientation which also includes education on gowning, gloving and scrub techniques.</p> <p>RESPONSIBLE PARTIES Director, Medical Staff Administration Director, Graduate Medical Education Perioperative RN Educator</p>	<p>Monthly (ongoing)</p> <p>Annually in July (ongoing)</p> <p>Annually in June (ongoing)</p> <p>2011 JUL 12 PM</p>	

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	Continued From page 3 member of the procedural care team (including anesthesia providers) at the time of, and during the procedure. Under Procedure of Surgical Verification, Letter B, no. 9 to 11 stated that, the procedure would not begin until every member of the team had agreed and all questions or concerns were resolved. When two or more procedures were being performed on the same patient, a time-out was to be performed to confirm each subsequent procedure before it was initiated. The attending anesthesiologist or anesthesia staff, RN Circulator/Scrub Technician or the attending surgeon would be responsible for conducting a time-out. Per clinical record review on 7/21/10, Patient X was admitted to the hospital on [redacted] 10 for debulking of a malignant tumor caused by testicular cancer (tumor of the male reproductive gland). Per the two operative procedure reports dated [redacted] 10, Patient X had two operative procedures, with physicians from four different medical departments of the hospital, during an approximately 12 1/2 hour surgery. Surgeon A performed an excision of liver lesions. Prior to removing the lesions the surgeon applied a retractor instrument to the upper abdomen to open the surgical incision wider. Surgeons C and B then started the second procedure of removing the tumors of the small bowel and around the aorta (biggest artery next to the heart), and removal of lymph nodes, the left kidney and the left testicle. Surgeons from the Colorectal Surgery Service (specialists in large bowel and rectum) "came in as intraoperative consults." Per the anesthesia record,		Policy changes were communicated to all perioperative staff by the Perioperative RN Educator during in-person educational meetings held weekly on Thursday mornings. Attendance is mandatory for all full time staff and is evidenced by sign-in sheets. Per-diem staff were educated via email which included "return receipts" to the Educator. Any per diem staff member not providing a "return receipt" was personally contacted by Educator and required to provide acknowledgment of education materials. MONITORING Daily monitoring of OR records (to ensure mandatory x-rays were properly performed in any case of unresolved counts) was undertaken to ensure continual compliance. Monitoring was continued until 100% compliance was achieved for 30 consecutive days. Results of monitoring were presented monthly to the OR, Organizational Performance, and Medical Executive Committees and Governing Body. RESPONSIBLE PARTIES: Director, Perioperative Services Perioperative RN Educator	07/30/10 08/15/10 02/07/11	

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2011 JUL 12 PM 7 H2

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	<p>Continued From page 4</p> <p>the surgery started at 0713 hours and lasted until 1940 hours.</p> <p>The Nursing Intraoperative Record, dated [REDACTED] 10, revealed that a first, second and final count was documented, but at unknown times and/or at what segment of the surgery. There was no count done when Surgeon A left the operating room and/or prior to Surgeons B and C beginning their surgical procedures. As per the hospital's P&P when more than one procedure would be done on the same patient, additional time-outs should be conducted to confirm each subsequent procedure and discuss any discrepancy, such as incorrect sponge counts. The three sets of count personnel (Circulating Nurses and Scrub Technicians) documented their break times; however, there was no additional count documented when they were relieved. There was no additional count documented during shift change among the incoming and outgoing staff to determine an accurate count of the sponges, instruments and sharps being used in the operative field, the back table and the unsterile field.</p> <p>Review of the Nursing Intraoperative Record, dated [REDACTED] 10, revealed that it was during the second count, at an unknown time and segment of the surgery, that an incorrect sponge count was determined. The bagged sponges were recounted and an additional count was initiated per hospital's P&P. An unidentified surgeon was notified and approved a request for an x-ray. However, no x-ray was taken at this time per documentation. The surgery was resumed and the third sponge count again was incorrect prior to the surgical wound</p>		<p>STAFF EDUCATION</p> <p>Perioperative staff were immediately inserviced on the requirement of separate time outs when two or more procedures were being performed on the same patient. Inservicing was also provided regarding the requirement of additional counts for procedures involving more than one incision and/or procedure on the same patient. Education was provided by the Perioperative RN Educator during in-person educational meetings held weekly on Thursday mornings. Attendance is mandatory for all full time staff and is evidenced by sign-in sheets. Per-diem staff were educated via email which included "return receipts" to the Educator. Any per diem staff member not providing a "return receipt" was personally contacted by Educator and required to provide acknowledgment of education materials.</p> <p>A list of newly credentialed faculty surgeons is sent monthly to the Perioperative Educator. The Perioperative Educator sends an email communication to the surgeon(s) summarizing the "Counts" policy. The email contains a "link" to the hospital's policy website which will enable the surgeon to have access to the entire policy. The email is tagged with a "return receipt" to ensure the Educator is able to validate the surgeon has received the email. Any emails without "return receipts" will be followed up the Educator.</p>	<p>07/30/10</p> <p>08/15/10</p> <p>08/15/10 (ongoing)</p>

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	Continued From page 4		<p>Page 5A (continuation from page 5)</p> <p>New residents/fellows are educated on the OR "Counts" policy upon arrival at the Medical Center. An email is sent to all incoming residents and fellows which summarizes the "Counts" policy. The email contains a "link" to the hospital's policy website which will enable the resident/fellow to have access to the entire policy.</p> <p>3rd and 4th year medical students are oriented to the OR and the "Counts" policy during their formal OR orientation which also includes education on gowning, gloving and scrub techniques.</p> <p>MONITORING Observational monitoring was implemented to assure continuous compliance with policy. Monitoring will remain in place until 100% compliance is achieved and sustained for 3 consecutive months. Results of monitoring will be presented to the OR, Organizational Performance and Medical Executive Committees and Governing Body.</p> <p>RESPONSIBLE PARTIES: Director, Medical Staff Administration Director, Graduate Medical Education Perioperative RN Educator</p>	<p>Annually in July (ongoing)</p> <p>Annually in June (ongoing)</p> <p>07/30/10 (ongoing)</p>

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	<p>Continued From page 5</p> <p>closure. A KUB (Kidney, Ureter, and Bladder) x-ray was taken on [REDACTED] 10 at 1840 hours. A KUB is a plain x-ray of the abdomen. It is often supplemented by an upright view of the chest (to rule out air or other problems under the diaphragm).</p> <p>The x-ray was read by Surgeon C not a radiologist. Per the operative report by Surgeon C, dated [REDACTED] 10, there was no evidence of a foreign body in the film taken and so the surgical incision was closed. Patient X went directly to ICU (Intensive Care Unit) and had another KUB x-ray taken on [REDACTED] 10 at 2140 hours.</p> <p>On [REDACTED] 10, the radiologist who reviewed the KUB x-ray taken in the Operating Room on [REDACTED] 10 agreed with the surgeon's findings. The same radiologist reviewed the second KUB x-ray, taken in the ICU, and reported a retained laparotomy sponge on the right upper quadrant of the abdomen, above the liver and under the diaphragm. The two chest x-ray views, taken on [REDACTED] 10 at 2341 hours, further confirmed the presence of the laparotomy sponge located high in the upper abdomen.</p> <p>On [REDACTED] 10, Patient X was brought back to surgery to retrieve the retained laparotomy sponge. Patient X, once again, was exposed to the risks and possible complications of anesthesia and surgery such as infection, bleeding, drug reactions, blood clots, paralysis, brain damage, heart attack or death. Surgeon C's operative report, when the retained foreign body was retrieved on [REDACTED] 10, stated "The sponge appeared to have been previously folded and was probably consistent with</p>		<p>POLICY REVISION</p> <p>The hospital's Policy & Procedure on "Counts-Sponge, Sharp, Instrument and Small Items" was immediately revised to require a full field image or images. If a retained item is not seen on the x-ray by the Attending Surgeon, then the surgeon or his/her designee (with an appropriate scope of practice) will contact the Radiology resident and ask for a review of the image(s). The Radiology resident will notify the surgeon if a retained item is visualized so it may be removed. If the resident does not see a retained item, an Attending Radiologist will review the image(s) and confirm there are no retained items per radiological exam. The circulating RN will document who read the x-ray and the outcome in the OR record.</p>	2011 JUL 12

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	Continued From page 5		<p>Page 6A (continuation from Page 6)</p> <p>Policy changes were communicated to all perioperative staff by the Perioperative RN Educator during in-person educational meetings held weekly on Thursday mornings. Attendance is mandatory for all full time staff and is evidenced by sign-in sheets. Per-diem staff were educated via email which included "return receipts" to the Educator. Any per diem staff member not providing a "return receipt" was personally contacted by the Educator and required to provide acknowledgement of education materials.</p> <p>A list of newly credentialed faculty surgeons is sent monthly to the Perioperative Educator by the Director, Medical Staff Administration. The Perioperative Educator sends an email communication to the surgeon(s) summarizing the "Counts" policy. The email contains a "link" to the hospital's policy website which enables the surgeon to have access to the entire policy. The email is tagged with a "return receipt" to ensure the Educator is able to validate the surgeon has received the email. Any emails without "return receipts" will be followed up by the Educator.</p> <p>New residents/fellows are educated to the OR "Counts" policy upon arrival at the Medical Center. An email is sent to all incoming residents/fellows which summarizes the Counts policy. The email contains a "link" to the hospital's policy website which will enable the resident/fellow to have access to the entire policy.</p> <p>3rd and 4th year medical students are oriented to the OR and the "Counts" policy during their formal OR orientation which also includes education on gowning, gloving and scrub techniques.</p> <p>RESPONSIBLE PARTIES: Director, Medical Staff Administration Director, Graduate Medical Education Perioperative RN Educator</p>	<p>07/30/10</p> <p>08/15/10</p> <p>08/15/10 (ongoing)</p> <p>Annually in July (ongoing)</p> <p>2011 JUL 12 PM 7 H2</p>

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	<p>Continued From page 6</p> <p>a sponge placed on retractor body wall at the time of the initial surgery."</p> <p>On 7/21/10 at 1300 hours, the Director of Perioperative Services was interviewed. She was unable to determine the times when the sponge counts were done and why there were no sponge count times indicated on the intraoperative record. She was unable to explain why there was no documentation of a change of shift count either.</p> <p>On 7/21/10 at 1430 hours, RN 6, one of the break relief nurses for Patient X, stated that she would request an additional count and an extra time-out every time there was a change of surgeons and between multiple procedures on the same patient to prevent retained foreign bodies, as written in the hospital's P&P.</p> <p>On 7/22/10 at 1530 hours, RN 7 stated that the incoming shift should be counting with the outgoing shift. RN 7 was unable to show per documentation when the shift count was done for Patient X. RN 8, at 1600 hours, verbalized counting the "countables" on the table during break relief for Patient X's surgery but acknowledged not documenting in the patient's record. As a circulator nurse, their goal was to keep the counting board current and accurate for the whole surgical team. Scrub Technician 1 agreed.</p> <p>The facility failed to follow their P&P for surgical sponge counts between procedures when two or more procedures were performed on the same patient, when there was a change of the final</p>		<p>A further review of the automated intraoperative record system (SIS) revealed that the SIS system automatically generates a time stamp each time a sponge count entry is made. The "time stamp" is retained in the system's data file, but it does not print on the hard copy of the intraoperative record. It is, however, available for data retrieval at all times.</p> <p>STAFF EDUCATION All staff received additional documentation training during the weekly Thursday morning in-person educational sessions conducted by the Perioperative Educator. Attendance at the educational meetings is mandatory for all full time staff and is evidenced by sign-in sheets. Per diem staff were educated via email which included "return receipt" requests to the Educator. Any per diem staff not providing a "return receipt" was personally contacted by the Educator and required to provide acknowledgment of education materials.</p>	<p>07/30/10</p> <p>08/15/10</p>

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Event ID: IUOF11

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8:45:31AM

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.