| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 050515 | A. BUILDING ______<br>B. WING ______ | 12/12/2011 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| KAISER FOUNDATION HOSPITAL - SAN DIEGO | 4647 ZION AVENUE, SAN DIEGO, CA 92120 SAN DIEGO COUNTY |

| (X4) ID PREFIX TAG | SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) | ID PREFIX TAG | PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) | (X5) COMPLETE DATE |
|---|---|---|---|---|

The following reflects the findings of the Department of Public Health during an inspection visit:

Complaint Intake Number:
CA00241706 - Substantiated

Representing the Department of Public Health:
Surveyor ID # 22363, HFEN

The inspection was limited to the specific facility event investigated and does not represent the findings of a full inspection of the facility.

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.

Informed Adverse Event Notification Health and Safety Code Section 1279.1 (c). "The facility shall inform the patient or the party responsible for the patient of the adverse event by the time the report is made."

The CDPH verified that the facility informed the patient or the party responsible for the patient of the adverse event by the time the report was made.

1279.1 (b) For purposes of this section "adverse event" includes any of the following:
1279.1 (b) (1) (D) Retention of a foreign object in a patient after surgery or other procedure,

T22 DIV5 CH1 ART3-70223(b)(2)
PLAN OF CORRECTION

1. Updated and implemented Operating Room policy and procedure entitled "Count and Documentation of Items Used in Surgical Procedure" to include:
   - All non-radiopaque towels not used for set up of back table, mayo stand and draping of surgical site will be removed from the sterile field before surgical incision.
   - After surgical incision only clearly identifiable white radiopaque towels will be used for duration of case.
   - An x-ray is obligatory prior to closing skin in the event of a significant unexpected event in the operating room e.g. massive blood loss unless contraindication of an x-ray is documented by the surgeon.

(X5) Complete date: Policy approved by Surgical Services Committee September 2010

Policy approved by the Surgical Services Committee and Medical Executive Committee.

Event ID:VIJR11 12/13/2011 9:21:21AM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Mary Ann Barner
TITLE: SVP / Executive Director
(X6) DATE: 12/28/11

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.

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 050515 | A. BUILDING ______ B. WING ______ | 12/12/2011 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| KAISER FOUNDATION HOSPITAL - SAN DIEGO | 4647 ZION AVENUE, SAN DIEGO, CA 92120 SAN DIEGO COUNTY |

| (X4) ID PREFIX TAG | SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) | ID PREFIX TAG | PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) | (X5) COMPLETE DATE |
|---|---|---|---|---|

Continued From page 1

intervention and objects present prior to surgery that are intentionally retained.

70223 (b)(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 administaation and medical staff where such is appropriate.

Based on interview and record review, the facility failed to ensure that Operating Room staff implemented their policy and procedure related to a complete count of towels used for one (1) sampled Patient (Patient A) during surgery. As a result, a blue towel was left undetected in Patient A's abdominal cavity for a period of 16 months. Patient A required a second surgery on [redacted]10 for removal of the retained blue towel from Patient A's abdomen.

Findings:

Patient A, a 69 year old female, was admitted to the facility on [redacted]09 following a 5 day history of abdominal pain according to the history and physical (H&P). Per the H&P, Patient A was diagnosed with cholelithiasis and choledocholithiasis (gallstones in the gallbladder and common bile duct).

On [redacted]09 Patient A was taken to the operating room (OR) for a Laparoscopic cholecystectomy and intraoperative cholangiogram (small tubes and

2. All members of the Surgical Team (Surgeons, Interventional Anesthesiologists, Operating Room RNs/Operating Room Circulator RNs, Scrub Techs) were in-serviced on the updated "Count and Documentation of Items Used in Surgical Procedure" policy and procedure to prevent the reoccurrence of a retained foreign object during a significant unexpected event in the operating room. — All staff in-serviced in February 2011

3. As part of the Surgical Services Department's orientation all newly hired operating staff will review the "Count and Documentation of Items Used in Surgical Procedure Policy". — Ongoing

4. The Nurse Assistant process is the process by which the Operating Room Circulator RN calls the Charge Nurse to assist during an unexpected event in the operating room. — All staff in-serviced by February 2011
   - All Operating Room Charge RN's/Operating Room Circulator RN's were in-serviced on the Nurse Assist process.

MONITORING

1. Perioperative staff audited 30 random surgical cases per month that involve a surgical procedure of an open cavity to ensure that all extra towels are removed from the surgical field prior to incision until 100% compliance is obtained for three months. — September 2010 to January 2011
   - Audit results reported to the Patient Safety and Risk Department.

RESPONSIBLE PARTIES
- Director, Perioiperative Services
- Physician Director of Surgical Services



LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Mary Lynn Barner | TITLE: SVP/Executive Director | (X6) DATE: 12-28-11

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.

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050515 | (X2) MULTIPLE CONSTRUCTION A. BUILDING ______ B. WING ______ | (X3) DATE SURVEY COMPLETED 12/12/2011 |
|---|---|---|---|
| NAME OF PROVIDER OR SUPPLIER: KAISER FOUNDATION HOSPITAL - SAN DIEGO | | STREET ADDRESS, CITY, STATE, ZIP CODE: 4647 ZION AVENUE, SAN DIEGO, CA 92120 SAN DIEGO COUNTY | |

| (X4) ID PREFIX TAG | SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) | ID PREFIX TAG | PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) | (X5) COMPLETE DATE |
|---|---|---|---|---|

**Continued From page 2**

cameras are inserted through tiny abdominal incisions to view and remove the gallbladder and study the common bile duct for further gallstones).

According to the [redacted]09 operative report, during the procedure, the surgeon encountered significant bleeding from a large branch of the hepatic artery. Because of the emergent situation the surgeon found it necessary to change the operation to an open cholecystectomy (large abdominal incision to remove the gallbladder) in order to clearly view the source of the excessive bleeding. Following the surgery Patient A was transferred to the ICU (Intensive Care Unit) and eventually discharged home on [redacted]09.

Patient A was readmitted to the facility on [redacted]10 with an abdominal mass suspicious for a retained foreign body (according to the discharge summary dated [redacted]10). According to the same discharge summary, a CAT (Computerized Axial Tomography a three dimensional X-Ray) performed on [redacted]10 revealed "A 14 cm mass...the appearance of a retained towel or sponge..." According to the operative report, on [redacted]10, Patient A had an exploratory laparoscopy (surgical opening of the abdomen for exploration) and removal of foreign body where a surgical blue towel measuring approximately 12 inches by 24 inches was removed from the abdominal cavity.

The [redacted]09 operative report and OR records for the first surgery were reviewed with administrative staff on [redacted]10. There were 3 physicians, two circulating nurses [one of the circulating nurses

Event ID:VIJR11 12/13/2011 7:58:14AM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Mary Ann Barnes — TITLE: SVP/Executive Director — (X6) DATE: 12-28-11

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.

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 050515 | A. BUILDING ______ B. WING ______ | 12/12/2011 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| KAISER FOUNDATION HOSPITAL - SAN DIEGO | 4647 ZION AVENUE, SAN DIEGO, CA 92120 SAN DIEGO COUNTY |

| (X4) ID PREFIX TAG | SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) | ID PREFIX TAG | PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) | (X5) COMPLETE DATE |
|---|---|---|---|---|

**Continued From page 3**

was not available for interview] and three scrub technicians for the case which lasted from 2:32 p.m. to 7:44 pm. The estimated blood loss during this procedure was 2 1/2 liters and a total of 5 units of blood were given during the surgery.

Physician 1 (the surgeon who performed both surgeries), spoke about Patient A on 9/27/10 at 1:30 p.m. The surgeon stated that Patient A had developed massive bleeding during the operative procedure on [redacted]09 and he immediately opened the patient and called for assistance from another general surgeon as well as a vascular surgeon. According to Physician 1 he did not recall using any towels during the operation only lap sponges (Radiopaque or X-Ray detectable sponges).

Circulating nurse (CN 1) was interviewed on 9/27/10 at 2:00 p.m. According to CN 1 the surgical towels are used to cover the mayo stands (sterile trays on a stand) and the back tables. CN 1 stated she had no idea how a towel was left in the patient, and did not recall anyone in the OR telling her that sterile towels were put in the abdominal cavity. According to CN 1, anything that goes in the patient should be accounted for and if it is called out to her, she marks it on the count board.

The scrub technician (ST 1) was interviewed on 9/27/10 at 2:30 p.m. According to ST 1 once the patient started bleeding the OR got very loud. According to ST 1 he kept calling for more lap sponges due to the blood loss. They were calling for more instruments and there was only one circulating nurse who was also trying to page the



LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Mary Ann Barnes | TITLE: SVP/Executive Director | (X6) DATE: 12-28-11

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.

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050515 | (X2) MULTIPLE CONSTRUCTION A. BUILDING ____ B. WING ____ | (X3) DATE SURVEY COMPLETED 12/12/2011 |
|---|---|---|---|

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| KAISER FOUNDATION HOSPITAL - SAN DIEGO | 4647 ZION AVENUE, SAN DIEGO, CA 92120 SAN DIEGO COUNTY |

| (X4) ID PREFIX TAG | SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) | ID PREFIX TAG | PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) | (X5) COMPLETE DATE |
|---|---|---|---|---|

**Continued From page 4**

surgeon on call, to assist Physician 1.

Scrub tech 2 [ST 2] was interviewed on 9/27/10 at 3:15 p.m. According to ST 2 the environment in the OR was very hectic. ST 2 stated it was very common for the surgeons to use towels under the liver to move the liver forward when repairing bleeding vessels such as the one in this case. ST 2 stated the policy would be to use the radiopaque towels but according to ST 2, the circulating nurse was not there to get the radiopaque towels. ST 2 stated he recalled one of the surgeons ( he couldn't remember which one) in the room taking a sterile towel from the mayo stand and using it to move the liver forward in order to stabilize the vessel for suture repair. ST 2 stated he yelled out "sterile towel in" but the circulating nurse (CN 1) wasn't in the room. ST 2 stated CN 1 had left to get more instruments/supplies for the surgery. ST 2 said he believed he did mention the fact that the towel was in the abdominal cavity to CN 1 when she came back into the OR but said it was so hectic that CN 1 didn't write it on the count board. ST 2 stated he was certain that the sterile towel he saw go in the patient's abdominal cavity came out. ST 2 said the sterile towel went in the abdominal cavity before repair of the bleeding vessel and stayed in until just before the close of the case but was not recorded on the count board. ST 2 further stated the surgeon was concerned about the count so the staff did a re-count before closing.

ST 3 was interviewed 9/27/10 at 3:45 p.m. and stated the only reason she was involved was to help CN 1 at the end of the case with the count. ST



LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Mary Ann Barnes | TITLE: SVP/Executive Director | (X6) DATE: 12-28-11

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.

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050515 | (X2) MULTIPLE CONSTRUCTION A. BUILDING ______ B. WING ______ | (X3) DATE SURVEY COMPLETED 12/12/2011 |
|---|---|---|---|

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| KAISER FOUNDATION HOSPITAL - SAN DIEGO | 4647 ZION AVENUE, SAN DIEGO, CA 92120 SAN DIEGO COUNTY |

| (X4) ID PREFIX TAG | SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) | ID PREFIX TAG | PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) | (X5) COMPLETE DATE |
|---|---|---|---|---|

Continued From page 5

3 stated she scrubbed in to count instruments with CN 1.

The facility's policy and procedure entitled "Count and Documentation of Items Used in Surgical Procedure," last revised 10/09 addressed the procedure for blue towels. According to the policy blue towels are to be included in the count under miscellaneous items. Further the policy clarifies under procedure number 4: "Foreign body placed inside the body cavity/vault that is not intended to be implanted will be audibly reported to the RN and documented on the count board" and under procedure number18; "...For any items placed inside a cavity that is not intended to be implanted, the circulator and scrub and surgeon will visually ensure of its removal and accounted for its entirety".

Patient A had unexpected bleeding during her surgery necessitating a change in the original planned laparoscopic procedure to an open abdominal surgery lasting longer than anticipated. ST 2 recalled observing a physician in the room place a non radiopaque towel under Patient A's liver, ST 2 yelled out towel in, however CN 1 was not in the operating room. ST 2 failed to ensure that CN 1 heard and recorded the use of the towel on the count board. Although ST 2 was sure he recalled seeing the towel come out, a towel, whether that towel or another unobserved or unrecorded towel was left in Patient A following surgery.

The facility's failure to ensure that OR staff followed



LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Mary Ann Barnes SVP/Executive Director — TITLE — (X6) DATE 12-28-11

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.

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 050515 | A. BUILDING ______<br>B. WING ______ | 12/12/2011 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| KAISER FOUNDATION HOSPITAL - SAN DIEGO | 4647 ZION AVENUE, SAN DIEGO, CA 92120 SAN DIEGO COUNTY |

| (X4) ID PREFIX TAG | SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) | ID PREFIX TAG | PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) | (X5) COMPLETE DATE |
|---|---|---|---|---|

**Continued From page 6**

their policy and procedure, by not recording the use of the towel(s) during the surgery on the count board, and ensuring a correct count prior to closure of Patient A's abdominal cavity 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 the 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).

Event ID:VIJR11 12/13/2011 7:58:14AM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: [signature] TITLE: SVP/Executive Director (X6) DATE: 12-28-11

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.