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

Complaint Intake Number:
CA00242591 - Substantiated

Representing the Department of Public Health:
Surveyor ID # 25720, 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.

The following reflects the findings of the California Department of Public Health during the investigation of COMPLAINT NO: CA00242591.

Inspection was limited to the specific complaint(s) investigated and does not represent the findings of a full inspection of the facility.

Representing the California Department of Public Health: Surveyor 2097, HFEN; and 8927, Medical Consultant.

Health & Safety Code Section 1280.1(c): For purposes of this section "immediate jeopardy" means a situation in which the licensee's

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<th>Plan of Correction for Complaint No. CA00242591</th>
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<td>How the correction will be accomplished, both temporarily and permanently:</td>
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<td>The Policy and Procedure, “Count of Sharps and Sponges” PTC-090 was revised to include the following:</td>
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**Counting process:**

The number of sponge counts for cesarean section patients are now defined as a minimum of four counts and the names of the counts have been changed to reflect the type of count (pre-count, cavity, closing and final) versus numbered (1,2,3,4)

Minimum numbers of sponge counts for other surgical procedures are also defined.

An extra count has been added to the process whenever a foreign implant (e.g. mesh) is inserted into a cavity.

The process for the sponge count has been changed to reflect that each sponge is visualized individually and separated from one another and the sponge “tail” is visualized, by the scrub tech and the circulator.
Continued From page 1

noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient.

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.

DEFICIENCY CONSTITUTING IMMEDIATE JEOPARDY

CCR, Title 22 DIV5 CH1 ART3- 70223(b) (2) - Surgical Service General Requirements.

(b) A committee of the medical staff shall be assigned responsibility for:
(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 appropriate.

The above regulation was NOT MET as evidenced by:

Based on observation, interview and medical record review, the hospital failed to ensure Policies and Procedures (P&Ps) governing surgical care were

The counting bags for laparotomy and raytec sponges are used uniformly.

If counts are incorrect and cannot be immediately reconciled, the Director or Manager (or designee) of the Unit is notified immediately, and staff are to implement the imaging process and search processes, prior to the patient leaving the operative suite.

The radiology/imaging process for intraoperative studies to evaluate the presence of foreign bodies has been revised to:

Specify the type of radiographic view used to detect the radiopaque element ("tail") of the sponge.

Define the repeat imaging procedures that are to be completed should the sponge not be visualized on the radiograph and the sponge has not been found.

Require that a second radiologist will be contacted to "overread" in cases where the counts are incorrect and the sponge is not visualized on the radiograph. In addition, the second radiologist will order additional imaging, if necessary.

Require that, in all emergency cases where counts were omitted, the imaging process defined above will be
 Continued From page 2

implemented. The hospital failed to ensure the implementation of the P&P for the counting of sponges during a surgical procedure for one patient which resulted in the patient undergoing a second surgery for the removal of a retained sponge (Patient 43). Patient 43 developed an abscess (infection) and bowel perforations which required surgery and an eight day hospitalization for treatment.

Findings:

On 9/8/10, review of the P&P for Count of Sharps and Sponges, revised 3/09, showed the sharps and sponges were counted in the OR (Operating Room) by the scrub nurse/OR Tech and the circulating RN (Registered Nurse):

* prior to the procedure to establish baseline counts;
* before closure of any body cavity or part there of (e.g. bladder, uterus);
* before closure of any deep or large incision; and
* immediately before the completion of the surgical procedure (e.g. skin closure). Additional counts might be indicated according to circumstances.

The medical record for Patient 43 was reviewed on 9/8/10. The patient was initially admitted to the hospital on [mask] 10. At 2156 hours on [mask] 10, Patient 43 had a C-section (cesarean section - delivery of an infant by a cut through the abdomen and uterus). Documentation on the physician's operative note showed there were no complications. The patient was discharged home with her infant on [mask] 10.

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**Education:**

All scrub techs and circulating nurses have completed a revised Skill-Specific Competency prior to the performance of their next case, which included the items in the corrective action above.

All scrub techs and circulating nurses have received training involving "Speak-Up for Patient Safety" and assertiveness training. Such training was also extended to contract staff members before any further cases were performed.

**The title of the person responsible for the correction:**

Vice-President of Patient Care Services

**Description of the monitoring process to prevent recurrence of the deficiency:**

All of the corrective actions above have been implemented.

A minimum of three cases per staff member were audited for compliance with the revised sponge count procedures. The Director, Manager (or...
Further review of the medical record for Patient 43 showed the patient presented to the ED of the hospital on 9/10. The ED physician documented the patient was seven weeks post C-section. The patient was assessed to have a hard painful area in the left lower abdomen and a 1 cm (centimeter) opening with purulent drainage (pus) in the previous C-section incision.

Review of the Computerized Tomography (CT) scan of the abdomen and pelvis done for Patient 43 on 9/10 showed a finding of an object in the left mid abdomen. A 5 x 8 cm mass was noted suspicious for a retained surgical sponge, possibly with bowel injury or abscess.

Patient 43 underwent surgery on 9/10 for removal of a foreign object. Review of the physician’s operative report showed dense adhesions (scar tissue) were found in the pelvis and lower abdomen with a hole in the mid jejunum (small bowel) and the sigmoid (descending) colon. The surgeons performed a small bowel resection and sigmoid colectomy (removal of two pieces of bowel).

On 9/8/10 at 1110 hours, the Manager for Maternal Child Health was interviewed. In attendance were the CNO and the L&D (Labor and Delivery) Clinical Supervisor. The Manager for Maternal Child Health stated interviews were conducted with OR Tech A and RNM on 9/4/10. The Manager stated these staff members were present for Patient 43’s C-section on 9/10. The Manager stated, in questioning OR Tech A, the tech stated she

designee) performed the audit. Any discrepancies observed were corrected and the staff member received additional training to assure competency.

Cesarean section cases were directly observed for a 30 day period for compliance with the process changes by the Department Director, Department Manager or Charge Nurse. Any discrepancies were immediately rectified for the protection of the patient.

Results were reported through the Performance Improvement and Patient Safety Committee with reports to the Medical Executive Committee and the Governing Board

Date that the immediate correction of the deficiency will be accomplished:

September 14, 2010

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.
Continued From page 4

usually did only three sponge counts during a C-section. The tech stated she would count sponges on the table initially and then would count again during the procedure before the uterus was replaced in the abdomen. The third count was conducted prior to the closure of the fascia (a general layer lining the walls of the abdominal cavity and surrounding the abdominal organs). The Manager stated RN M stated she did not usually work with OR Tech A and thought it strange not to do a fourth count before the final skin closure. RN M stated however the counts had been correct.

The non electronic Intraoperative Record form used in the L&D OR was reviewed with the Manager for Maternal Child Health. The form showed an area for documentation of the pre count with boxes to check for yes or n/a (not applicable) for sharps, sponges and instruments. In addition were lines designated as the first, second and third counts. There was a check off box to show the count was conducted with a line for signatures of the scrub person and RN circulator. There was no area for documentation of the time, or at which point in the procedure the count was conducted. When asked, the Manager stated the form did not show a count documented as the “fourth count.” The Manager stated staff were trained to do four counts during a C-section.

The Intraoperative Record dated [redacted], for Patient 43 was reviewed. The form was completed to show the initial use of sharps, sponges and instruments and the subsequent first, second, and third counts completed with a correct count.
The hospital's official transcripts of the interviews with OR Tech A and RN M, conducted on 9/4/10, were reviewed on 9/13/10. OR Tech A stated she usually did only three counts. The tech stated, in the main OR four counts were done, but in the L&D OR suite "we only do three and that was how I was trained." Following a discussion with the Manager of Maternal Child regarding the hospital's P&P Counts of Sharps and Sponges, which required the four counts, OR Tech A stated she sometimes did four counts. The tech stated she would do a fourth count if the count was not correct before the closing of the skin. RN M stated she remembered that three sponge counts were done. The RN stated the patient had more bleeding than usual so more sponges had been added to the field, but the sponge counts had been correct. RN M stated, as the incision was being closed she thought to herself there should be another count. RN M stated however, she felt it was the OR tech's area of expertise, and she did not feel comfortable saying anything. When asked to confirm the number of sponge counts during Patient 43's C-section on 9/10, RN M stated a fourth count was not done. Both staff members were asked, if the count was correct, why do you think this occurred? Both OR Tech A and RN M stated they were not sure, as it did not make sense. RN M stated that perhaps the count was not correct before the closure of the fascia. Both OR Tech A and RN M agreed that a fourth count before the closure of the skin would have revealed a missing sponge.

The facility's failure to ensure implementation of the
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P&P for counting of surgical sponges during a surgical procedure 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(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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