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

Complaint Intake Number: CA00529409 - Substantiated

Representing the Department of Public Health: Surveyor ID # 2581, 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 1280.3(g): 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.

Fresno Heart and Surgical Hospital - RFO

The following reflects the findings of the Department of Public Health-Licensing and Certification, during an investigation of an Entity Reported Incident.

Entity Reported Incident Intake Number: CA00529409-Substantiated

Representing the Department of Public Health: Surveyor ID # 31505, HFEN and 32851, HFEN

The inspection was limited to the specific hospital event investigated and does not represent the

See attached Plan of Correction
freetext
Nursing Service Policies and Procedures

70213 (a) (4) (d)

(a) Written policies and procedures for patient care shall be developed, maintained and implemented by the nursing service.

(4) (d) Policies and procedures which require consistency and continuity in patient care, incorporating the nursing process and the medical treatment plan, shall be developed and implemented in cooperation with the medical staff.

Based on interviews, clinical and administrative document review, the hospital failed to follow the Operating Room (OR) policy and procedure for OR-Counts in the OR when the Cardiac Catheterization Lab (Cath Lab) staff failed to use a kick bucket (trash can for used gauze sponges) or hanging bags (containing pockets to separate and place each individual gauze sponge) during a procedure on Patient (Pt) 1 on 3/3/17 which resulted in a gauze sponge being left in the surgical site.

This failure resulted in Pt 1 returning to the Cath Lab 27 days later, on 3/30/17 for a second surgery where a surgical gauze sponge was identified as a retained foreign object. This required subsequent hospitalization, and caused preventable pain, injury
and harm to Pt 1.

Findings:

Pt 1's clinical record indicated he was diagnosed with a cardiac illness that required an implantable Cardiac Defibrillator (ICD - a device placed in the chest in order to deliver a shock to the heart when an abnormal heart rhythm is detected). On 3/3/17 Pt 1 underwent a procedure in the Cath Lab to replace the ICD generator (battery). Pt 1 was discharged home on 3/4/17 with instructions to follow-up with Medical Doctor (MD) 1 in one week.

On 4/10/17 at 9:55 a.m., during an interview and concurrent record review, the Cath Lab Manager (CLM) stated on 3/3/17, an ICD generator was placed in Pt 1. A review of the document titled, "Procedure Log" dated 3/3/17 indicated prior to the procedure, the Cardiovascular Technician (CV Tech, assists doctors during Cath lab procedures) 1 and the Circulating Registered Nurse (CRN, assists in managing the nursing care, coordinates the needs of the surgical team) counted (verifying the number of instruments, gauze sponges and needles used during the procedure) and confirmed 20 gauze sponges were available for use during the procedure. The "Procedure Log" indicated 10 additional gauze sponges were added during the procedure, with CV 1 and the CRN confirming the count. The CLM stated prior to closing the surgical incision, a final count was conducted. The "Procedure Log" indicated 30 gauze sponges were counted by CV 1 and the CRN after the procedure was completed.
On 4/10/17 at 11:30 a.m., during an interview, MD 1 stated Pt 1 had an ICD placed about 5-6 years ago and it was time for a new ICD generator. MD 1 stated the procedure on 3/3/17 included making an incision (cut) into the chest wall so the ICD could be removed, its generator replaced and then the ICD replaced by slipping it back under the skin. The incision was closed with sutures (stitches). MD 1 stated Pt 1 came to his office for a follow-up visit one week after the procedure and he noticed a small amount of discharge from the side of the incision. MD 1 stated Pt 1 was given a prescription for antibiotics and told to follow-up if there was an increase in swelling or discharge from the incision. MD 1 stated a week later, Pt 1 returned to the office with symptoms of discharge from the incision. MD 1 stated Pt 1 was evaluated and told to continue the antibiotics. MD 1 stated when Pt 1 returned a week later, for incisional discharge, he thought the incision was not healing, and he needed to find out why there was still discharge from the site. Pt 1 returned to the hospital on 3/30/17 and MD 1 performed an incision into the ICD surgical site and discovered the gauze sponge. MD 1 stated, "I had put the gauze in there to stop the bleeding on 3/3/17, which is the only reason it would be there. I perform the surgical procedure and the staff account for the instruments and sponges. I was very surprised to open the pocket [incision] and find a gauze in there; it has never happened to me."

A review of the document titled, "Cardiology Operative Report", dated 3/30/17 indicated, "The patient recently underwent defibrillator placement. The patient was noticed to have drainage from the
pocket [incision] site. The patient was referred for pocket [incision] revision...An incision was made at the site of the defibrillator. The defibrillator pocket was reached. The defibrillator was explanted. The patient has pus drained from the defibrillator pocket [incision]. Also there is an incidental finding, it is found that the patient had a previously placed Ray-Tec gauze [brand name for the gauze sponge] in the defibrillator pocket [incision]. The specimen was sent for culture..."

On 4/10/17 at 2 p.m., during an interview, Pt 1 stated, "I went to the doctor and he decided to replace the defibrillator [generator]. I came home and it [meaning the surgical site wound] wouldn't heal. I got a hold of the doctor and kept going back, and they found a gauze [sponge] inside me. I was as sick as a dog, I had pus running out of me, and I was vomiting and coughing. When I tried to lie down, the pus ran out of me and soaked everything. I am still suffering right now. I have pain in my left side, and I am coughing up phlegm. When I got sick, for three weeks he looked at the wound and it wouldn't heal, it was still oozing and I was still coughing."

On 4/11/17 at 8 a.m., during an interview, CV Tech 1 stated on 3/3/17 she was assisting MD 1 with the procedure. CV Tech 1 stated she conducted the count of the gauze sponges with CRN 1 prior to the start of the case and there were 20 gauze sponges for use on the table. CV Tech 1 stated during the procedure, "I try to keep the used sponges in a pile together, but sometimes the sponges fall on the floor. I try to gather all the sponges as MD 1 is
finishing the procedure, and lay them out at the foot of the procedure table or on the scrub table. I go through and I count them, and the CRN will watch the count.” CV Tech 1 stated, “I remember the sponges were a gelatinous mess, all gobbled together with blood and clots, and maybe one sponge was counted as two. Whoever counted with me agreed with the count, and MD 1 is right there with me as I count, so he is aware of the count.” CV Tech 1 stated she was aware Pt 1 returned to the Cath Lab on 3/30/17 with a retained sponge, and stated “I know we counted, I know he [Pt 1] came back, but I don’t know what happened.” CV Tech 1 stated after the incident the policy and procedure was reviewed. CV Tech 1 stated the staff were not following the OR policy of using kick buckets or hanging bags during the procedure to ensure the count was correct.

On 4/11/17 at 8:50 a.m., during an interview, CV Tech 2 stated on 3/3/17 he was documenting Pt 1’s case in the procedure log from the monitor room. CV Tech 2 stated he could not visually see the procedure or the gauze sponge count from the monitor room, and only documented information relayed to him via microphone by staff in the room. CV Tech 2 stated 20 gauze sponges were relayed to him as the count before the procedure, by CV Tech 1. CV Tech 2 stated during the case CV Tech 1 relayed to him that 10 additional surgical gauze sponges were added to the table, and post procedure CV Tech 1 relayed to him that 30 sponges were accounted for in the final count. CV Tech 2 stated the Cath Lab team should have used a kick bucket and hanging bag during the
procedure, and they do now.

On 4/11/17 at 9:30 a.m., during an interview, the CLM stated the Cath Lab staff were not trained directly in the OR, even though procedures were performed using counts consistent with OR standards. The CLM stated there was not a Cath lab specific policy and procedure for counts when the sponge was detected on 3/30/17, so the OR policy and procedure were reviewed. The CLM stated after the policy and procedure review she realized the staff was not using kick buckets to collect discarded sponges and hanging bags to count each individual sponge in the Cath Lab, and they needed to for compliance with policy and procedure for the hospital.

On 4/11/17 at 9:35 a.m., during an interview, CRN 1 stated he was the circulating RN in the room on 3/30/17. RN 1 stated, "When the incision was opened up it looked like an infection was starting. Things stopped when it was discovered what the issue was. There was a moment of clarity about what was going on, and no words were said. MD 1 just pulled out the sponge and looked at it." RN 1 stated, "I have been here 10 years and never seen this happen."

On 4/17/17 at 7:58 a.m., during an interview, the Clinical Supervisor (CS) stated he was monitoring Pt 1's procedure on 3/30/17. The CS stated CV Tech 2 called him into the room during the procedure and pointed to the sponge telling him, we just took this out of the incision. The CS stated he had never seen a gauze sponge left in an incision. The CS
stated the Cath Lab staff should follow the OR policy and procedure for all surgical cases and after review, realized the Cath Lab staff were not following it. The CS stated the Cath lab should have been using kick buckets and sponge hangers and they did not for Patient 1 on 3/3/17.

On 4/17/17 at 8:25 a.m., during an interview, CRN 3 stated she was circulating RN during Pt 1's procedure on 3/3/17. RN 3 stated she could not remember anything out of the ordinary with the case, just 10 extra sponges were added, and the count was correct when the case was complete. CRN 3 stated after the sponge was discovered in Pt 1 on 3/30/17 she was very disconcerted (upset) about the incident. She stated she had not had any refreshers on the OR policy while working in the Cath Lab and after review, realized the kick buckets and sponge hangers were not being used.

On 11/22/17 at 9:31 a.m., during an interview, Chief Nursing Officer (CNO) stated the Cath Lab follows the Association of periOperative Registered Nurses (AORN) national standards of care for patients in the OR and the hospital policy and procedure which includes the use of kick buckets and hanging bags. The CNO stated after a previous OR incident, the policy underwent changes corporate wide, and was sent to the staff for review. The CNO stated, "If you don't think it affects you, you really don't read it. Face to face education should have been given to the Cath Lab staff when the changes in the policy were made regarding the use of kick buckets and gauze sponge hangers, and education was not provided [to the Cath Lab staff]."
The hospital policy and procedure which follows AORN guidelines, titled, "OR-Counts in the OR" dated 3/27/14 indicated, "II. Countable Item: Any surgical item that could potentially be left inadvertently in the patient... Countable items include sponges... The RN Circulator is to pro-actively oversee and participate in safety measures with the entire perioperative team and be aware of and accurately account for all items during the procedure... The Scrub person is to maintain an organized sterile field... Maintain awareness of the location of all soft goods... The surgeon(s) and surgical assistants are to maintain awareness of all soft goods... Communicate placement of surgical items into the wound to the perioperative team for notation... Perform a methodical wound exploration when closing counts are initiated... The concurrent count is visualized and vocalized by both persons counting... Hanging sponge counters are to be used on all cases where raytechs [gauze sponges] or lap sponges are used and counted. When an item is added to the sterile field during the case, it is to be counted by the person who opened it, together with the Scrub person and added to the count sheet or count board... IV. The Scrub person, when removing used sponges from the surgical field during the case, must open up each sponge completely and carefully deposit it in a designated lined bucket. Use a dedicated sponge holder rack... Collect sponges throughout the case, separate and put them into pockets of the hanging sponge counter. All sponges—used and unused sponges—must be in hanging sponge counters at the end of the case to have a correct final count and to be able to perform
team verification...The Scrub and Circulator count all items visually, verbally and concurrently...

The hospital failed to follow their policy and procedure for OR-Counts in the OR during the replacement of an ICD in Patient 1 on 3/3/17. This failure directly lead to a surgical sponge being retained in Patient 1 for 27 days. The retained sponge directly lead to an additional surgical procedure on 3/30/17 to remove the sponge and additional hospitalization for antibiotic therapy. The hospital's failure resulted in preventable pain, injury and harm. The failure to follow the hospital's policy and procedure for OR-Counts in the OR directly lead to the licensee's noncompliance with one or more requirements for licensure.

The hospital failed to prevent the deficiency (ies) as described above which 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 1280.3(g).
Attachment for Plan of Correction

FACILITY ID: 040001397
PENALTY NUMBER: 040014355

The statements made on the plan of correction are not an admission and do not constitute agreement with the alleged deficiencies herein.

This plan of correction constitutes Fresno Community Hospital and Medical Center dba Fresno Heart and Surgical Hospital written credible allegation of compliance for the deficiencies noted.

Fresno Heart and Surgical Hospital (FHSH) is committed to providing excellent quality of care and takes patient safety very seriously. We welcome the opportunity to provide feedback to the alleged deficiencies. Upon learning of this event FHSH took immediate action to investigate and take actions starting March 30, 2017, including the following:

- Disclosed to the patient and treated by the Surgeon
- Incident reported to the Chief Nursing Officer (CNO), Facility Chief Medical Officer (CMO), System CMO, and Chief Executive Officer (CEO) of the facility by Patient Safety Manager.
- Reported to System COO, CEO and the President of the Medical Staff by the System CMO.
- Reported to the Board of Trustees by the System CMO
- Reported to Surgery Advisory and Facility Executive Committee
- Reported to CDPH in a timely manner by Patient Safety
- Patient Safety completed a Root Cause Analysis in partnership with the Cath Lab staff and physicians with action plans completed.

1. The corrective action to be taken for each individual affected by the deficient practice, including any system changes that must be made;

a) The policy, OR – Counts in the OR (ID# 11152), was reviewed by the Facility CNO and Cath Lab Manager on March 30, 2017. The Cath Lab Manager then reviewed the policy and practice with all Cath Lab staff and face-to-face re-education on the counting process and expectations. Education points included location of policy, what is a countable item, what is an official count, what is a relief count, what is a radiopaque item, what is a non-radiopaque item, what is a retained surgical item, what is a retained foreign body, what cath lab...
procedures require to have counts, when are counts performed, what order to count, review of count sheet and white boards, who will maintain count sheet, how to use hanging sponge counter, how to verify counts, and proper documentation. All Cath Lab staff provided a returned demonstration for the expected counting process. This education was started on April 3, 2017 and completed by all Cath Lab staff by April 17, 2017.

b) The Cath Lab onboarding skills checklists were updated May 1, 2017 to include review of policy, OR – Counts in the OR (ID#11152) to ensure new hires are familiar with process and understand the expectations.

c) The policy, Electronic Authentication of the Medical Record (ID#11919), was reviewed by the Cath Lab Manager and then with all Cath Lab staff who were then re-educated on the documentation procedures and expectations within the electronic health record. This education was started on April 3, 2017 and completed by all Cath Lab staff by April 17, 2017.

d) Effective April 3, 2017 the Cath Lab Manager implemented a mandatory counting worksheet to assist with documenting the counting process.

e) To support the accurate counting process, better visualization of sponges, and to be compliant with policy, a dedicated lined metal sponge kick buckets and hanging sponge counters were added to all Cath Lab procedure rooms by March 31, 2017.

f) On April 11, 2017 the facts, summary, and monitoring plan of this event was reviewed at the FHSH Cardiology Advisory Committee (CAC) with emphasis to policy adoption and expectations on counting process.

g) On May 31, 2017 a summary of this event was presented at the FHSH Facility Executive Advisory Committee (FEAC). It was noted to the committee that immediate action plan was put into place regarding the OR Counts process, including the use of hanging sponge counter and sponge kick bucket in the Cath Lab.

2. The title or position of the person who will monitor the corrective action and the frequency of monitoring; and

a) On April 3, 2017 and continuing for four weeks, the Cath Lab Manager observed 100% of all Cath Lab cases that used sponges for proper counting procedure and documentation. The monitoring resulted in 100% compliance with expectations for Cath Lab counting processes including: preliminary counts, closing counts and final counts; use of metal kick buckets and hanging sponge bags; use of counting worksheets; and proper documentation in the electronic health record.

b) To ensure continued compliance the Cath Lab Manager performed random monthly chart reviews from May 2017 to September 2018, resulting in 100% compliance for the past 17 months. Compliance results were shared in the quarterly leadership meeting with Assistant Chief Nursing Officer on the following dates: September 15, 2017; November 17, 2017; January 12, 2018; April 20, 2018; July 20, 2018.

c) The Cath lab Manager or designee will continue to monitor 10 randomly selected charts each month through the end of October 2018, to ensure sustained compliance. If non-compliance
occurs, coaching and counseling will occur and monitoring will continue for another three months or until 100% compliance is achieved.

d) Monitoring results will be reported at the CRMC Practice and Compliance Committee, Facility Executive Committee, and Corporate Quality Counsel for quality assurance, governing body oversight and accountability.

3. Dates each corrective action will be completed.

   a) Dedicated lined metal sponge kick buckets and hanging sponge counters were added to all Cath Lab rooms by March 31, 2017.
   
   b) New count worksheets were made available by April 3, 2017.
   
   c) Cath Lab staff completed face-to-face education on the policy, OR- Counts in the OR (ID#11152), and Electronic Authentication of the Medical Record (ID#11919) on April 17, 2017.
   
   d) On September 21, 2018 the Cath Lab Manager will present to the FHSQ Quality and Patient Safety Committee the results of monitoring, which have met 100% compliance.