The following represents the findings of the California Department of Public Health during:

Entity Reported Incident visit # CA00175238.

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

Representing the California Department of Public Health:

HSC 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

Title 22 70223
(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.

On 1/16/09, the hospital's surgical team performed the mandatory TIME OUT prior to commencing

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The following table outlines the summary of deficiencies found during the inspection:

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<thead>
<tr>
<th>ID</th>
<th>PREFIX</th>
<th>TAG</th>
<th>SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)</th>
<th>ID</th>
<th>PREFIX</th>
<th>TAG</th>
<th>PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)</th>
<th>(X5) COMPLETE DATE</th>
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surgery on Patient R's brain. The entire surgical team failed to recognize that the right side of Patient R's head had been incorrectly marked by Surgeon 1 prior to the surgery. The surgical procedure was initiated, a portion of the right side skull was removed, and the brain was exposed and examined. The surgical team realized the error when they were unable to find bleeding in the right side of the brain. The team failed to recognize that the left side of Patient R's head was the correct surgical side. This resulted in the 93 year old, Patient R, having to endure extended time in surgery under general anesthesia while the surgical team performed surgery on the correct side.

On 1/29/09 the closed medical records of Patient R were reviewed along with policy and procedure titled Universal Protocol for Surgical and Invasive Procedures (#46832.99).

Documented in the history and physical was that Patient R, a 93 year old man who presented to the hospital emergency department on 1/13/09. Physical examinations were completed by the attending and consulting physicians, along with CAT scan exams dated 1/13/09, 1/14/09, 1/15/09, and 1/16/09. The physicians concluded that Patient R was suffering symptoms consistent with bleeding in the left side of the brain. The diagnosis of sub-dural hematoma (bleeding in the brain) was assigned to Patient R, and documented throughout the medical record to have been located on the left side of the brain.

Patient R was observed over the next two days, and on 1/15/09 physicians determined that surgery was required to remove the hematoma from the brain's left side. On 1/16/09 Patient R was taken to

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

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 2

surgery.

The intra operative record provided that six members of the surgical team were present in the operating room suite on 1/16/09 at 11:20 a.m. According to the intra operative record documentation, Surgeon 1, Surgeon 2, Anesthesiologist 1, RN 1, RN 2, and ST 1 halted at 11:20 a.m. to perform the required TIME OUT.

The TIME OUT procedure consisted of the entire surgical team stopping the surgical process prior to making an incision to assure that they were doing the correct surgery, on the correct patient, on the correct body part and side. As defined in the hospital's procedure titled, Universal Protocol for Surgical and Invasive Procedures (#48632.99) the definition of TIME OUT: "Time out means that after admission to the operating room/procedure room, to OR and Time Outs are conducted properly with all staff engaged in induction of anesthesia (if applicable), completion of prepping and draping, and immediately prior to the start of the procedure, the entire team must pause or interrupt what they are doing and focus their attention and verbally verify that the identity of the patient is correct. Additionally, the correctness of the procedure to be done, and the site/side for that procedure must be confirmed."

The entire surgical team all agreed to the procedure and then began the surgery, but on the wrong (right) side of the head. The surgical team proceeded to remove a section of bone from the skull of Patient R, and attempted to locate the bleeding (hematoma) in the right brain area. The operative report dated 1/16/09 and dictated by Surgeon 1 provided the following: "Initially, the right side of the head was turned up

4) SICU staff education on Universal Protocol policy and procedure, emphasizing patients who transfer directly from SICU to surgical suite and need for site marking (if appropriate) prior to leaving SICU

Responsible Party: SICU Manager and OR Manager
Date Completed: 01/29/09

5) Universal Protocol Audit Tool developed and implemented. Observational audits are conducted to ensure site marked prior to entry to OR and Time Outs are conducted properly with all staff engaged in process.

Responsible Party: OR Managers or designee
Date Completed: 01/22/09

6) Added redundant process to ensure Time Out performed immediately prior to incision by placing an orange sterile towel over the proposed site of the incision that has "TIME OUT" printed on it as a visual reminder to perform time out.

Responsible Party: OR Managers or designee
Date Completed: 01/30/09
Continued From page 3

and clipped of hair. The right side was prepared and draped in the usual sterile manner.... The dura was incised over the frontal lobe, and no hematoma was encountered. At this point the studies were re-reviewed and the side of the head was found to be the incorrect side.... The patient was repositioned with the left side of the head turned up and resting on the horseshoe headrest, the left side of the head was clipped of hair, prepared and draped in the usual sterile manner.

On 1/29/09 at 2:00 p.m. RN 1 was interviewed. RN 1 stated that in the surgical suite on 1/16/09, Surgeon 1 prepared the head of Patient R by clipping the hair on the entire head then marking the right side of the skull with a U shaped line, and oriented the head with the right side up. RN 1 stated that she continued to prepare the right side surgical site by cleaning the surgical area with cleansing agents using betadine scrub paint solution. RN 1 also provided a drawing representing the head of Patient R and how the Surgeon 1 marked the right side of the skull. RN 1 then stated that she read from the surgical consent three times stating that surgery was to be on the left side of the head.

The entire surgical team failed to recognize during the Time Out procedure that the surgeon marked the wrong surgical site. Despite reading aloud the surgical consent three different times before the start of the surgical procedure surgery was performed on the wrong site.

During an interview on 1/29/09 at 8:30 a.m., Hospital Administrative Representative 1 stated that Patient R went directly from the intensive care unit to the surgical suite where Surgeon 1 marked the

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incorrect right side of Patient R's skull. Family Member 1 who was present in the hospital room prior to the surgery on 1/16/09 was interviewed on 2/5/09 at 2:20 p.m. Family Member 1 stated that Surgeon 1 came and visited Patient R and the family members prior to surgery in room 15, and that no markings of Patient R were done by Surgeon 1 during the pre-operative room visit. The hospital's policy and procedure (P&P) titled, Universal Protocol for Surgical and Invasive Procedures (#46832.99) was reviewed on 1/29/09. The P&P provided that the marking of the patient will be performed "before the patient is moved to the location where the procedure will be performed". This aspect of the P&P was not followed.

In addition to performing surgery on the wrong side of Patient R's head, the following errors were noted in the intra-operative medical record documentation for the surgical procedure.

1. The documentation in the intra-operative record provided that RN 3 had done the pre-operative cleaning and preparation of Patient R's surgical site with chlorhexidine and alcohol. During the interview with RN 1 it was stated that RN 4 entered the documentation into the medical record. RN 4 had incorrectly entered RN 3's name and the incorrect cleaning solution of chlorhexidine and alcohol. The pre-operative cleaning solution was Betadine scrub paint solution as stated by RN 1. A subsequent interview done with RN 4 on 1/2/09 at 2:20 p.m. corroborated that he had documented in the intra-operative report the wrong name (RN 3) and the incorrect cleaning solution. Statements made by RN 1 and RN 4 provided that RN 3 was never in the operative suite on 1/16/09.


LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITe (X6) DATE
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2. Entries into the intra operative record related to the "PreOp Checklist" denoted that Patient R arrived to the surgical service "ambulatory" (walking) and was "Admit from: Home." Both of these entries were incorrect as Patient R had been in the hospital for three days and arrived to the surgical suite in a hospital bed. Documentation in the hospital's emergency department record had Patient R arriving via ambulance on 1/13/09.

3. The section of the Intra Operative Care Plans provided that one of the intra operative safety outcomes were to ensure that Patient R's "Skin, other than incision or non-targeted areas, is unchanged from admit to discharge from the OR." This outcome was documented as MET in the medical record. The fact that the incorrect side of Patient R's skull had the bone removed verified that the safety issue was not met.

Then entire surgical team failed to ensure that the correct surgical side was operated on 1/16/09, thereby exposing Patient R a second surgical incision, and prolonged time in surgery under general anesthesia.

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Medical Record Errors in Intra-Operative Documentation for the Surgical Procedure:

9) RNs 1 and 4 completed mandatory education and counseling on importance of accurate charting in medical record per SGH policies and specifically addressing wrong RN noted in Operative Record, wrong skin prep documented and incomplete plan of care documentation initiated.

Responsible Party: Director, Surgical Services and OR Manager
Date Completed: 01/19/09

10) Following RNs 1 and 4 completion of education and counseling, next 10 cases for each RN was audited for correctness and following SGH charting policies.

Responsible Party: OR Manager or designee
Date Completed: April 23, 2009