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

Complaint Intake Number:
CA00247960 - Substantiated

Representing the Department of Public Health:
Surveyor ID #: 25338, 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.

John F Kennedy Memorial Hospital-CA247960

Administrative Penalty (AP)
A014 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.

70223: Surgical Service General Requirements
(b) A committee of the medical staff shall be assigned responsibility for:
(2) Development, maintenance and implementation

The plan of correction is prepared in compliance with federal regulations and is intended as JFK Memorial Hospital (the "hospital") credible evidence of compliance. The submission of the plan of correction is not an admission by the facility that it agrees that the citations are correct or that it violated the law.

Organization Minutes:
The confidential and privileged minutes are being retained at the facility for agency review and verification if required.

Exhibits:
All exhibits including revisions to Medical staff Bylaws, reviewed/revised or promulgated policies and procedures, documentation of staff and medical staff training/education are retained at the facility for agency review and verification upon request.

Policy & Procedures:
The Chief Nursing Officer and the Director of Clinical Quality Improvement reviewed and revised the Universal Protocol for Preventing Wrong Site, wrong Procedure, Wrong person Surgery policy to clearly delineate the time out process, site marking and the requirements for an accurate procedural consent form. The Chief of Staff reviewed the revisions on behalf of the Medical Staff.

Event ID: X0XG11
2/14/2012 5:07:37PM

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.
Training:
The Director of Education assigned all direct care providers in Surgical Services a mandatory web based education module on Patient Safety Alert 6 Universal Protocol and Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery. The web based module also addresses how to conduct a proper time out and how to handle discrepancies during the time out process. This information has been incorporated into new surgical services and invasive procedure areas employee orientation; and is part of annual re-orientation.

Monitoring:
The Director of Surgical Services or designee and Directors of invasive procedural areas conduct 30 observational audits per month on the time out process of both inpatient and outpatient procedures to ensure all required elements are addressed appropriately. Any identified issues are rectified immediately.

Data is forwarded to Quality Management Department for trending and analysis. This information is sent to Quality Council, Medical Executive Committee and the Governing Board for review and action as required.

Findings:
On December 2, 2010, at 10:10 a.m., an initial investigation was conducted for an entity reported incident. A concurrent interview with the Chief Nursing Officer (CNO) and Director of Quality and Risk (OQR) indicated Patient A received the wrong surgery on [redacted] 2010. Patient A received a tongue-lig release (cut performed under the tongue) instead of tongue lesion resection (removal of a growth on the tongue). In addition, this failure resulted in Patient A being exposed to the risks of bleeding and infection, and unnecessary exposure to the risks associated with anesthesia that was needed to perform the right procedure.
Continued From page 2

growth on the tongue)

On January 10, 2011, Patient A's record was reviewed. Patient A, a six-year-old male was brought in by his parents for an outpatient surgery.

The "Pre-Operative History and Physical" dated 2010, performed by Surgeon 1, was reviewed and indicated, "Chief Complaint: Tongue lesion lesion almost 1 x (by) 1 cm (centimeter) over the center of the tongue...Plan for resection of the tongue lesion (mass) with reconstruction...." There was no indication that a tongue-tie release was considered.

The "Consent to Surgery" dated 2010, at 10 a.m., indicated, "Resection of tongue lesion.

The "Surgical Pre-Operative Assessment" dated 2010, was signed by Surgeon 1. The record did not indicate whether there were any changes or any updates to the original H&P (History and Physical).

The "Pre Op Surgical Check List" dated 2010, filled out by the surgical licensed nurses, indicated, "Resection of tongue lesion.

The "Pre-Anesthesia Evaluation" dated 2010, at 10 a.m., signed by Anesthesiologist 1 was reviewed and indicated, "Pre-op dx (diagnosis): tongue tie lesion release tongue tie resection tongue lesion (the word tie, release tongue tie were lined out and initialed)."

Other Corrective Actions:
The Chief Nursing Officer and the Director of Clinical Quality Improvement met with the surgeon involved in the case and discussed process failures, opportunities for improvement, and the requirements of an appropriate time out. The surgeon agreed to see all patients in the preoperative area.

The Chief of Staff sent the non-compliant surgeon a letter that he must actively participate in the time out process, including the medical staff's expectation that full engagement, including active participation, is a requirement of the time out process.

Responsible Person(s):
Chief Nursing Officer
Director Clinical Quality Improvement
Director of Surgical Services
Chief of Staff

Disciplinary Action:
Non-compliance with corrective action by hospital staff will result in immediate remediation and appropriate disciplinary action in accordance with the hospital's Human Resources policies and procedures.
### Statement of Deficiencies and Plan of Correction

**Provider/Supplier/Clinical Laboratory Identification Number:** 050534

**Multiple Construction:**
- A Building
- B Wing

**Date Survey Completed:** 05/18/2011

**Name of Provider or Supplier:** JOHN F. KENNEDY MEMORIAL HOSPITAL

**Street Address, City, State, Zip Code:** 47111 Monroe St, Indio, Ca 92201-6739 RIVERSIDE COUNTY

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### Summary Statement of Deficiencies

Each deficiency must be preceded by full regulatory or LSC identifying information.

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The "Anesthesia Record" dated  [redacted] 2010, with anesthesia start time of 10:05 a.m., indicated, "Surgical Procedure: release of tongue tie..."

The "Operative Report" dated  [redacted] 2010, at 10:26 a.m., indicated, "Preoperative and Postoperative Diagnoses: Ankyloglossia (connection of the tip of the tongue to the bottom of the mouth)/tongue tie and speech disorder..." The record further indicated, "...The patient with a history of tongue tie/ankyloglossia. The release of tongue was indicated...Alternatives, benefits and risks...were already explained to the mother. She understood and agreed to proceed. The tongue was extruded and step by step with using cautery, the entire tongue was released..."

The "Universal Protocol Checklist Team Time-out" dated  [redacted] 2010, initiated at 10 a.m., indicated the "Scheduled Procedure" was "Removal of Tongue Mass, possibly fibroma..." The record indicated a "time-out" was performed at 10:19 a.m., which ensured each team member verbally verified the following:
- Correct patient identity,
- Correct side and site,
- Agreement on the procedure to be done

The "Intraoperative Nursing Record" dated  [redacted] 2010, with surgery start time at 10:20 a.m., indicated, "Preop (Preoperative) Diagnosis: Tongue mass, most probably fibroma...Procedure: Release of Tongue Tie..."

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**Event ID:** X0XG11  2/14/2012  5:07:37PM

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The "PACU (Post Anesthesia Care Unit) Record" dated 2010, with time in at 10:28 a.m., was reviewed and indicated, "Procedure: Release of tongue tie."

The record further indicated the following:

a. At 10:28 a.m. - "A 6 year old male admitted via gurney from OR (Operating Room) accompanied by (Anesthesiologist 1) and (RN [Registered Nurse] 1)"

b. At 10:32 a.m. - "Parent at bedside - mother asking about surgery. Advised she could see in his mouth under the tongue. She said no it is on the top of the tongue... Parents upset and mother keeps stating he was supposed to have tongue lesion removed and not anything was discussed about tongue tie..."

On January 11, 2011, RN 1 was interviewed. She stated she was the circulator nurse during the surgery for Patient A. She stated she verified preoperatively the procedure to be tongue mass resection. She stated she had conversations with Surgeon 1 about Patient A regarding medications that needed to be started with the patient. RN 1 stated the procedure was verified and confirmed with informed consent signed by the parent, which indicated tongue mass resection. RN 1 stated, "At no time tongue tie release was discussed with Surgeon 1 prior to the procedure." RN 1 stated the patient was brought in to the OR and when Surgeon 1 came in to the OR, "time-out" was initiated and confirmed the procedure as tongue mass resection. She stated, "Surgeon 1 said, Okay, okay."

### Event ID: X0XG11

2/14/2012 5:07:37PM

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

**TITLE**

**DATE**

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The surgeon proceeded to the mouth and performed the surgery. She stated Patient 1 was then brought to the PACU and report was given to the RN 2.

On January 11, 2011, RN 3 was interviewed and stated she was the second circulator in the case for Patient A. She stated she heard Anesthesiologist 1 verified the procedure with the mother as tongue mass resection in the pre-op area. Patient A was brought to the OR for the procedure shortly after that RN 3 recalled RN 1 going in and out of the other OR to verify with Surgeon 1 the IV (intravenous) orders for Patient A. She recalled the surgeon indicated to RN 1 that IV was not needed because the procedure was a short procedure. RN 3 stated "time-out" was performed to verify that the procedure was a tongue mass resection. She stated the team members verified the type of procedure according to what was written on the white board. She stated the information, which included the type of procedure, was written on an erasable board according to what was indicated in the informed consent. RN 3 stated Surgeon 1 did his procedures in a quick pace. She stated, "(Surgeon 1) stops now (during the time-out to verify) after this happened." She stated the members that definitely needed to verify the "time-out" were the surgeon, anesthesiologist, and the primary circulator.

On January 11, 2011, at 12:55 p.m., the COA (Chief of Anesthesiologist) was interviewed. He verified Anesthesiologist 1 was unavailable for interview (on vacation). He stated he spoke with Anesthesiologist 1 regarding the case and...
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particularly the "Pre-Anesthesia Evaluation" which had information that was lined out. He stated Anesthesiologist 1 stated she had written, "tongue tie...release tongue tie" prior to speaking with the parent in the preoperative area. As soon as she verified the procedure with the mother and the informed consent as "tongue lesion..resection tongue lesion," she put a line through and wrote the right preoperative diagnosis and proposed operation. He stated the "Anesthesia Record" was brought in the OR where the anesthesiologist documented the activity in the OR.

The "Anesthesia Record" for Patient A dated 2010, with a start time of 10:05 a.m., was reviewed with the COA. He stated he was unaware that the record indicated, "release tongue tie." He was unable to explain why the record was left as "release of tongue tie" when the pre-anesthesia evaluation was corrected and indicated resection of the tongue lesion instead of tongue-tie release.

On January 12, 2011, at 10:45 a.m., a phone interview was conducted with Surgeon 1. He stated he recalled RN 1 coming in (while he was in another case) and verified some IV antibiotic orders for Patient A. He gave orders to cancel the antibiotics for Patient A thinking antibiotics were not usually ordered for a tongue-tie release procedure and may be the reason why the nurse was verifying the antibiotic orders. He stated, "Nothing is better than honesty...do not recall any time-out." He stated there could have been two possible reasons why this happened. He stated,
Continued From page 7

"Either time-out was not done or it was done, but I could not recall what procedure was said," Surgeon 1 stated if the team members knew what was scheduled for Patient A (a tongue lesion resection), nobody questioned, "Where is the specimen?" Surgeon 1 stated Patient A had a scar tissue under the tongue and the tongue-tie release was indicated "anyway." When the surgeon was asked whether he examined the patients in the pre-op area prior to the surgery, he stated, "Usually, I don't examine anybody. I sometimes visit...in this case, there was no time to do pre-operative visit. From now on, I need to see the patient prior to surgery."

On January 12, 2011, at 9:05 a.m., RN 4 (a PACU nurse) was interviewed regarding the flow of patients from surgery through PACU. She stated the PACU received a schedule of surgeries for the day. The PACU RN will be informed at least 10 minutes in advance before the patient was transferred to the PACU from the OR. The OR RN and anesthesiologist brought the patient in the PACU and gave report to the receiving PACU RN. The PACU RN verified the report with the Operative Report and record of the patient RN 4 stated she worked the day when the incident occurred. She stated she overheard the OR RN (RN 1) gave RN 2 (PACU nurse who received Patient A) report. She stated the report given by RN 1 to RN 2 was that Patient A had a tongue-tie release.

On January 13, 2011, at 11:15 a.m., a phone interview was conducted with RN 2 (PACU nurse who received Patient A). She stated the PACU nurses were given at least 10 minutes notice prior...
Continued From page 8

to receiving a patient from the OR. She stated, included in the notice, special endorsements were given when receiving a pediatric (child) patient. Information given did not include the procedure(s) performed on the patient. She stated report was given when the patient was brought in to the PACU. She stated on the day Patient A had his surgery, she recalled the patient being brought in by RN 1 and Anesthesiologist 1 to the PACU. She stated the report given to her (could not recall if both the RN and anesthesiologist gave report) was that Patient A underwent a tongue-tie release. She was also given report that the patient’s mother wanted to be at the patient’s bedside in the PACU. RN 2 stated when the mother asked about the patient’s surgery, she told the mother she could go ahead and check under the tongue, knowing the surgery performed was a tongue-tie release, which was what was given in report. RN 2 stated that was when the mother questioned why she was being directed to look under the tongue when the surgery was on the top of the tongue. RN 2 stated that was when RN 1 went and got Surgeon 1 to talk to the family. She stated she documented “Release of tongue tie” in the “PACU Record” because that was what was given to her in the verbal report, which was verified through the post-op report.

On January 19, 2011, at 11:50 a.m., a phone interview was conducted with Patient A’s mother. She stated the wrong surgery was performed to her son. She stated her son had appointments and was seen by Surgeon 1 on February 14, 2010. On February 14, 2010 (first appointment with Surgeon 1) was to have the tongue lesion checked.
Continued From page 9

The 2010 visit was for the pre-operative preparations. She stated on the day of surgery, Anesthesiologist 1 came in the pre-op area and discussed the process with her, including verifying the type of surgery. She stated Surgeon 1 did not see her son in the pre-op area at any time. Her son was brought in the OR and after 10 to 15 minutes, she was called to the PACU area. In the PACU area, she asked the nurse how the surgery was. The nurse responded, "The skin was clipped off," which was confirmed by the anesthesiologist who was at the bedside. She stated her son woke up and asked her son to open his mouth and stick his tongue out. She stated she still saw the tongue lesion on the tongue and questioned it. Surgeon 1 was called to verify the surgery, which verified that a tongue-tie release was performed. She asked the surgeon why the tongue lesion was not removed. She stated the surgeon stated, "What lesion... That's so small we didn't even notice it (talking about the lesion)..." She stated the surgeon decided to bring her son back in the OR to do the right surgery.

On January 13, 2011, at 10:20 a.m., the CNO and DQR were interviewed regarding the wrong surgery performed on Patient A. The CNO stated the facility identified the "time-out" did not appropriately occur. She stated the RN should have stopped the Surgeon and performed the "time-out" to verify all the information.

The facility policy titled, "Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery" effective June 4, 2005, was...
The policy further indicated:

a. "Pre-Procedural. The physician or designee performing the procedure in conjunction with the patient shall clearly mark the procedure side/site with the word "Yes" to enhance the reliability of the process. To avoid confusion, the person performing the procedure shall state the side/site and point to it with the patient. If the patient is a minor, the patient's legal representative (parent, legal guardian) shall work with the person performing the procedure to identify the procedural side/site."

b. "Pre-Procedural. The surgeon/physician, LIP or his/her designee performing the procedure is ultimately responsible for the verification process and shall verify the surgical site..."

c. "...Prior to performing the procedure, the surgical/procedural team will take a moment ("time out") Time-out must be immediately performed before starting the procedure. The time-out process shall be conducted in the location where the procedure will be done and shall involve the entire operative team. The team shall verbally verify the following Agreement on the procedure to be done..."; and

d. "Verification The physician or Licensed Independent Practitioner (LIP) shall discuss the..."

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Continued From page 11

operative/invasive procedure with the patient before the anesthesia/moderate sedation. The patient shall verbalize agreement of the correct procedure and surgical site, and the discussion and patient verbalization shall be documented in the medical record."

The policy further indicated, "...Prior to performing the procedure, the surgical/procedural team will take a moment ("time out") Time-out must be immediately performed before starting the procedure. The time-out process shall be conducted in the location where the procedure will be done and shall involve the entire operative team. The team shall verbally verify the following: Agreement on the procedure to be done. All components of the above process shall be completed and documented on the verification checklist."

The facility's failure to follow their policy and procedure, to preoperatively verify the site of surgery during the "time-out" process and to conduct preoperative patient examination by the surgeon to ensure the right surgery, 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