Complaint No. CA00201143

The investigation was limited to the specific complaint/self reported event investigated and does not represent the findings of a full inspection of the facility.

Representing the Department of Public Health:

Health & 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.

70233 - Anesthesia Service General Requirements

(a) Written policies and procedures shall be developed and maintained by the person responsible for the service 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 policies and procedures shall include provision for at least:

(3) Safety of the patient during the anesthetic period.

This rule is not met as evidenced by:

The facility failed to ensure that safety measures were taken in the operating room during a surgical event.

A043 - 70233 Anesthesia general Requirements

Written policies and procedures shall be developed and maintained by the person responsible for the service in consultation with other appropriate health professionals and administration. Policies shall be approved by the governing body. Procedures shall be approved by the medical staff where such is appropriate. The policies and procedures shall include provision for at least:

(3) Safety of the patient during the anesthetic period.

1. Temporary corrective action taken:
   a. No use of BiPAP oxygen delivery in the operating room.
   b. Root Cause Analysis (RCA) conducted immediately. Operating room sequestered to determine cause of device related incident. The review was conducted by the Director of Surgical Services and the Risk Manager and attended by the Safety Officer as well as other necessary staff. Device factors, external factors, support system failures, and user errors were all reviewed which identified fire and burn as the mechanism of injury.
   c. Responsible person: Director of Surgical Services
   d. Completion date: 09/09/09

2. Permanent corrective action:
   a. Mandatory education for Surgical Services staff and Respiratory Therapy staff on Surgical Fire Safety Lecture and Video and Fire Evacuation Drill, and Hands-on Fire Extinguisher Training.
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Procedure. As a result, Patient A suffered burns on his face after a flash fire occurred when staff used the electrosurgery equipment near the patient’s face mask which provided oxygen under positive pressure.

Findings:

Patient A was admitted to the facility’s emergency room on 9/2/09 with diagnoses that included altered level of consciousness and respiratory failure per the history and physical. Patient A was placed on BiPAP Mask ventilation (bi-level positive airway pressure, a noninvasive means of assisting oxygen and ventilation) and sent to the intensive care unit.

On 9/8/09, due to increasing respiratory problems, Patient A was sent to the operating room for a tracheostomy (surgical construction of an opening in the trachea for the insertion of a catheter or tube to facilitate breathing). The tracheostomy was to be performed under local anesthesia with BiPAP mask ventilation.

The operative report, dated 9/8/09 was reviewed. According to the operative report, oxygen that was passing around the edges of the BiPAP mask leaked onto the operative site and was ignited by the electrosurgery, [a surgical device that uses electrical current to cause tissue destruction] causing a flash fire. The fire lit up the sterile drapes and Patient A sustained burns to his face and singe to the hair.

According to the nursing notes, Patient A sat up procedure. As a result, Patient A suffered burns on his face after a flash fire occurred when staff used the electrosurgery equipment near the patient’s face mask which provided oxygen under positive pressure.

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According to the nursing notes, Patient A sat up
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(under local anesthesia) after the fire started. The OR staff extinguished the fire with water and patting the drapes.

A plastic surgeon was called to the operating room, by the surgeon. According to the plastic surgeon's notes, Patient A sustained first and second degree burns on the face, including the chin, the cheeks, the ears, and the forehead as well as singeing of the eyelashes.

Patient A's anesthesiologist (Physician 1) was interviewed on 10/14/09 at 1:00 p.m. According to Physician 1, Patient A was sent to the operating room on 6 liters of oxygen via mask. On arrival to the operating room, Patient A had decreased oxygen saturations and needed to be placed back on the BiPAP machine. Due to unfamiliarity with the BiPAP Vision machine (oxygen source for the BiPAP), Physician 1 requested the Respiratory Therapist [RPT] to be present in the operating room to assist with the Vision machine and BiPAP support. Physician 1 recalled asking the RPT if there was an oxygen leak.

The RPT was interviewed on 10/8/09 at 10:00 a.m. According to the RPT, whenever BiPAP ventilation is used there will always be an oxygen leak, and not until the leak is over 25 liters/minute is it of concern to RPT. According to the interview, the RPT rarely went to the OR and was not accustomed to OR room procedure. The RPT was not aware of what electrocautery was until after the fire.

The Chief of Medical staff for Quality Assurance
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(Physician 2) was interviewed on 9/9/09 at 10:00 a.m. Physician 2 stated it was unusual to use BiPAP in the operating room setting, stating that usually patients brought to the operating room for a tracheostomy were already intubated. Physician 2 stated that in those cases where the patient was already intubated, the oxygen was turned off and changed to air prior to the electrocautery being used. According to Physician 2, Patient A had a very difficult airway, due to limited range of motion in both the neck and mouth.

Physician 2 stated that the operating room staff were focused on the need for an airway and had overlooked the fact that the leaking oxygen coupled with the electrocautery posed a fire hazard. Physician 2 further stated that the procedure could have been done without the use of electrocautery.

The facility's failure to provide safe care related to the use of oxygen and electrocautery for Patient A in the operating room 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).

Event ID: NFHP11 1/1/2010 8:32:50AM

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

TITLE

DATE

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.