**AMENDED**

The following reflects the findings of the Department of Public Health during investigation of COMPLAINT NO: CA00169178.

Investigation was limited to the specific complaint(s) investigated and does not represent a full inspection of the hospital.

Representing the Department of Public Health: [Redacted] MD.

DEFICIENCY CONSTITUTING IMMEDIATE JEOPARDY

§70213(a) Nursing Service Policies and Procedures
(a) Written policies and procedures for patient care shall be developed, maintained and implemented by the nursing service.

§70215(c) Planning and Implementing Patient Care
(c) The nursing plan for the patient's care shall be discussed with and developed as a result of coordination with the patient, the patient's family or other representatives when appropriate, and staff of other disciplines involved in the care of the patient.

The above regulations were NOT MET as evidenced by:

Based on interviews, a review of a self-reported adverse event and review of a medical record, the nursing service failed to:

1. Re-education with the nursing staff began the evening of 11/6/08 and was ongoing until all staff who would be assigned to care for a patient with an EVD had received re-education. 11/21/08

2. Immediate post-operative care for a patient with an EVD will occur in the Pediatric Intensive Care Unit. 11/10/08

3. Completed a review of national standards of best practice regarding care of the pediatric patient with an EVD and incorporated these standards into the CHOC Nursing policy and procedure. 12/12/08


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

[Redacted] 4/1/2009

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 1

ensure the development and implementation of policies and procedures for the accurate monitoring and reporting of output rates and critical values such as color, consistency and fluid volumes, from ventriculostomy drainage devices to the physician. The ventricles of the brain are the internal fluid filled chambers separating the brain hemispheres. Cerebrospinal fluid (CSF) is a clear fluid that circulates about the brain and spinal cord. Blockage or obstruction to flow of the CSF results in rising intracranial fluid pressure (hydrocephalus) with distention of the ventricles and compression of brain tissue. A ventriculostomy is a tube inserted into the ventricles of the brain to assist with proper drainage of CSF. In addition, the hospital failed to ensure the nursing staff properly implemented and evaluated the care of Patient A. The hospital failed to ensure the nursing staff promptly notified the physician when there was a change in the drainage from Patient A's ventriculostomy. As a result of these failures, Patient A's brain function changed and the patient was experiencing brain injury as a result for insufficient blood flow to the brain.

Findings:

On 11/14/08, a review of the medical record for Patient A revealed that Patient A came to the hospital emergency room on 11/06/05. The patient was alert and active. Patient A underwent a surgical procedure to remove ventriculo-peritoneal shunt hardware on

4. Mosby Pediatric Collection of online (electronic) Nursing policies, procedures, nursing skills and reference system purchased to assist in the development and maintenance of written policies.

5. Mosby Pediatric Collection online system provides a competency and skill validation component for all policies and procedures which will be monitored on a quarterly basis by Nursing Service through the Nursing Committee Structure. Person Responsible for Correction: Executive Director Acute Care Services
Continued From page 2

11/08/08. A ventriculo-peritoneal shunt is a catheter inserted into the ventricle of the brain, connected to tubing that drains the internal fluid from the brain into the abdomen. The shunt is required and essential because of obstruction to normal flow of the fluid, usually resulting from a structural, congenital abnormality of the drainage system of the brain.

Further review of the medical record revealed that following surgery, Patient A was taken to and observed in the PACU, from 1108 hours until 1230 hours. The PACU nursing notes revealed no documentation or recording of ventricular fluid drainage in the medical record. Interviews with the Director of Regulatory Affairs and documents provided by the Risk Management Department revealed that the neurosurgeon instructed nursing staff that if any drainage would be observed, since he had drained all the fluid from the brain, during insertion of the new ventricular catheter. However, there was no written documentation of communication with the nursing staff, physician orders, or a policy and procedure in place to direct nursing staff regarding the normal or usual output of ventricular fluid, appearance, or consistency of the fluid. There was no policy and procedure to provide guidance to the nursing staff about critical values for fluid volumes, color, consistency, and rates of fluid drainage to be reported to the physician.

1. Staff re-educated on the requirements of documenting in the electronic medical record information related to the patient’s initial assessment and reassessments, nursing diagnosis, plan, intervention, and evaluation. The content included discussing with the neurosurgeon their expectation regarding CSF drainage, since the amount of drainage expected is case specific.

2. Immediate post-op care for a patient with an EVD will occur once in the PICU since the volume of patients with an EVD is variable and actual cases in the neurosurgical department is less than 2 per month. The neurosurgical department as a whole has at least 2 to 3 surgical inpatient cases per week.

Patient A was then transported from the PACU to the nursing unit for post-operative care at approximately 1230 hours on 11/06/08. Observations documented by the nursing staff, providing direct care for Patient A, of CSF/ventricular fluid drainage, indicated that 12.0 cc were noted at 1600 hours on 11/06/08, 4.0 cc at 1800 hours and 1.0 cc at 1900 hours. There was no documentation of drainage from the tube at 2000 hours. At 2100 hours 3.0 cc was documented. There was no output recorded for 2200 hours. When requested, the facility was unable to produce written guidelines or directives for nursing, to assess if these fluid volumes were normal.

Interviews with the Medical Director of the hospital and the Risk Manager conducted on 11/14/08 at approximately 1100 hours revealed no nursing instructions or policy and procedures for the nursing staff to assess ventricular fluid output volumes, color, appearance that were in place to provide guidance for the hospital nursing staff. When asked regarding the number of cases with similar surgical procedures, it was stated by both representatives from the hospital, that ventricular drainage procedures were common at the hospital, with 2-3 such surgical cases in the neurological unit, each week. It was stated by both representatives that the nursing staff were trained, with documented competencies reviewed, to care for these patients. However, when asked to produce policies to manage and observe ventricular fluid volumes or critical

<table>
<thead>
<tr>
<th>3. Mosby Pediatric Collection of online (electronic) Nursing policies, procedures, nursing skills and reference system purchased to assist in the development and maintenance of written policies.</th>
</tr>
</thead>
<tbody>
<tr>
<td>12/08</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4. Mosby Pediatric Collection online system provides a competency and skill validation component for all policies and procedures which will be monitored on a quarterly basis by Nursing Service through the Nursing Committee Structure. Person Responsible for Correction: Executive Director Acute Care Services</th>
</tr>
</thead>
<tbody>
<tr>
<td>12/12/2008</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>1. Recommendation made to Neurosurgical Department that surgeons placing an intraventricular shunt document in the operative report the presence of drainage post placement and/or document via imaging study proper placement within the ventricle. Person responsible for Correction: Chief Medical Officer</th>
</tr>
</thead>
</table>

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 disclosed to the Nursing home, the above findings and plans of correction are disclosed to the facility. If deficiencies are cited, an approved plan of correction is require to continue program participation.
values for the fluids or appearances of the fluids, the policy produced failed have written directives for the nursing staff about normal CSF fluids and output and abnormal results to report to the physician.

According to interviews with the Risk Manager conducted at 11:00 hours on 11/14/08, Patient A's ventriculostomy drainage tubes were clamped close to the patient's head (proximal) and farther down the tube (distal), in order for the mother of Patient A to hold and comfort Patient A on 11/06/08. According to the Risk Manager, the transfer of the patient from her crib to the mother occurred at approximately 2:45 hours.

During transfer of Patient A from her mother back to the crib, the registered nurse unclamped the distal clamp of the ventriculostomy drainage catheter at approximately 2200 hours, but did not unclamp the proximal clamp of the ventricular drainage tube. The Risk Manager stated that this portion of the drainage catheter remained fully clamped, preventing normal CSF flow into the external drainage collection bag.

According to the Risk Manager, and the policy and procedure for ventricular drainage catheters, in place at the hospital, the nursing staff failed to open both stopcocks to ensure appropriate ventriculostomy drainage, to prevent hydrocephalus (buildup of fluid in the brain and increased intracranial pressure).
CA准备的声明和纠正计划

<table>
<thead>
<tr>
<th>(X1) PROVIDER/SUPPLIER/Clinic Identification Number:</th>
<th>(X2) MULTI BUILDING/ WING</th>
<th>(X3) DATE SURVEY COMPLETED</th>
</tr>
</thead>
<tbody>
<tr>
<td>053304</td>
<td></td>
<td>11/14/2008</td>
</tr>
</tbody>
</table>

**NAME OF PROVIDER OR SUPPLIER**: CHILDREN'S HOSPITAL OF ORANGE COUNTY

**STREET ADDRESS, CITY, STATE, ZIP CODE**: 455 SOUT MAIN STREET, ORANGE, CA 92868 ORANGE COUNTY

**SUMMARY STATEMENT OF DEFICIENCIES**

Continued From page 5

At 2200 hours, nursing assessments in the medical record revealed that the patient was "lying quietly". A "late entry" recorded on 11/07/08 revealed "no CSF/Ventricular fluid drainage was noted at 2200 hours." "Solid matter was noted in the external ventricular drainage (EVD) system." "EVD lowered to floor to see if CSF moved in the tubing." "Patient noted to have slowed rate of breathing with deep gasps of air." A "Code White" for resuscitating Patient A was called at 2323 hours.

According to interviews with the Risk Manager, the Medical Director of the hospital, and a review of the "Cardiopulmonary Resuscitation flow sheet" Patient A was being manually ventilated at the time of initiation of the Code. According to these interviews, the physician intubating Patient A observed that the EVD had dropped to the floor and no fluid drainage of movement was seen in the tubing. Patient A was intubated at 2342 hours.

The physician who intubated Patient A ordered a "Stat CT Head Scan", to determine the location of the ventricular catheter. This procedure was performed at approximately 2352 hours. The written interval note by the physician revealed "Tip of EVD is in the brain parenchyma, not in the ventricular system." (This note indicated that the ventricular drainage catheter was not in the ventricle of the brain, but within the substance of the brain.)

---

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

**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 discernible 30 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 discernible 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 6
This indicated that, at some point, the ventricular catheter had been dislodged or pulled from its normal location within the lateral ventricle of the brain to a point in the brain tissue. No CSF/Ventricular fluid drainage was possible since the tube was not in the desired location).

MD #1, the attending neurosurgeon was notified at approximately 2400 hours, and came to the hospital. At approximately 0100 hours on 11/07/08, a bedside insertion of a new ventricular catheter was performed. The procedure note, dictated by MD #1 revealed "A new ventriculostomy catheter inserted with prompt return of CSF (cerebrospinal fluid) under markedly elevated ICP (intracranial pressure)." (This note indicated that the brain was under severe pressure, with markedly elevated fluid pressure as a result of the fluid being unable to be drained externally).

Following the procedure, Patient A remained obtunded. An MRI was ordered and performed on 11/08/08. This study revealed evidence of a "global hypoxic ischemic injury". (During the buildup of intracranial pressure, blood perfusion of the brain was impaired, leading to the hypoxic injury to the brain). Patient A was not responsive and an inpatient at the hospital on 11/14/08.

The violation(s) has caused or is likely to cause, serious injury or death to the patient.