

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050609	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 10/12/2010
NAME OF PROVIDER OR SUPPLIER Kaiser Foundation Hospital - Orange County - Anaheim		STREET ADDRESS, CITY, STATE, ZIP CODE 3440 E La Palma Ave, Anaheim, CA 92806-2020 ORANGE COUNTY		
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	<p>Pharmaceutical Service General Requirement.</p> <p>(c) A pharmacy and therapeutics committee, or a committee of equivalent composition, shall be established. The committee shall consist of at least one physician, one pharmacist, the director of nursing service or her representative and the administrator or his representative.</p> <p>(1) The committee shall develop written policies and procedures for establishment of safe and effective systems for procurement, storage, distribution, dispensing and use of drugs and chemicals. The pharmacist in consultation with other appropriate health professionals and administration shall be responsible for the development and implementations of procedures. Policies shall be approved by the governing body. Procedures shall be approved by the administration and medical staff where such is appropriate.</p> <p>The above regulations were NOT MET as evidenced by:</p> <p>Based on interview and medical record review, the hospital failed to follow their policy and procedure (P&P) regarding the administration of alteplase and heparin medications (two anticoagulant medications used to dissolve and prevent blood clots) within 4 hours and 10 minutes of each other. Patient 1 was administered bolus (whole) dose and continuous dose of heparin intravenous (into the vein) infusion within 4 hours and 10 minutes after the administration of alteplase. Patient 1 received two potent anticoagulant medications, alteplase</p>		**See Page 3 for beginning of Action Plans	

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	<p>and heparin (both medications enhance the risk of bleeding), resulting in intracranial (within the skull) hemorrhage (bleeding) and death on [REDACTED] 10, two days after the hospital admission on [REDACTED] 10.</p> <p>Findings:</p> <p>The hospital's P&P titled Inpatient Anticoagulant Protocol, revised as of 10/08, showed for non-hemorrhagic stroke (disruption of blood flow to an area of the brain due to obstruction or bleeding) patients who have received alteplase, heparin is contraindicated in the first 24 hours after the administration of alteplase, and not to give heparin in the first 24 hours after the administration of alteplase.</p> <p>The manufacturer's guidelines for alteplase showed the most common complication encountered during alteplase therapy is serious intracranial and gastrointestinal (intestinal) bleeding which could result in significant disability or death. The concomitant use of heparin and alteplase may contribute to serious bleeding problems.</p> <p>According to Lexi-Comp's pharmacology website, thrombolytic (to dissolve blood clots) drugs such as alteplase may enhance the anticoagulant effect of heparin in increasing the risk of bleeding.</p> <p>Patient 1's medical record review was conducted on 10/12/10.</p> <p>The History and Physical report dated [REDACTED] 10, showed the patient was admitted to the Irvine</p>		<p>1. Action Plan: Policy "Inpatient Anticoagulation Protocol" was revised to include: For TIA and Stroke patients: Non-Hemorrhagic Stroke Patients who have received Alteplase (tPA):</p> <p>"Heparin is contraindicated in the first 24 hours after the end of the infusion of Alteplase (tPA). Do not give any Heparin in the first 24 hours." Pharmacy staff re-educated on Policy "Inpatient Anticoagulation Protocol."</p> <p>Person Responsible: Inpatient Pharmacy Directors</p> <p>Date Completed: 10/2010: Pharmacy staff re-educated 10/15/2010: Policy was approved by the Pharmacy and Therapeutics Committee 10/22/2010: Policy was approved by the Executive Committee</p>	<p>10/2010</p> <p>10/15/10</p> <p>10/22/10</p>

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	<p>campus of the hospital on [REDACTED] 10, due to syncope (temporary loss of consciousness and posture). The patient was fully alert and able to recount what medications he was taking.</p> <p>The CT scan (Computed Tomography scan is an imaging method that uses x-rays to create pictures of cross-sections of the body) of the head dated [REDACTED] 10, showed no evidence of intracranial hemorrhage (bleeding).</p> <p>The MRI (Magnetic Resonance Imaging is a test that uses a magnetic field and pulses of radio wave energy to make pictures of organs and structures inside the body) of the brain dated [REDACTED] 10 at 1245 hours, showed evidence of a large area of infarct [an area of tissue that undergoes necrosis (narrowing) as a result of obstruction of local blood supply]. Again, no evidence of intracranial hemorrhage was noted.</p> <p>The Multi-Disciplinary Note dated [REDACTED] 10 at 1332 hours, showed the patient was assessed to have weakness to the left upper and lower extremities, slurred speech, and right facial drooping. The patient stated he could not feel when the nurse touched his right hand.</p> <p>The blood test result dated [REDACTED] 10 at 1535 hours, showed the patient's APTT (activated partial thromboplastin time; a blood test used to detect abnormalities in blood clotting and monitor the effect of anticoagulants such as heparin to determine the blood's thinness) was 28 seconds (reference range: 25-35 seconds).</p>		<p>2. Action Plan: Directive "Heparin Dosing and Monitoring Protocol: Interventional Imaging" was developed to include: "Guidelines for dosing of Heparin during Interventional Radiology procedures" Radiology staff educated on Directive "Heparin Dosing and Monitoring Protocol: Interventional Imaging"</p> <p>Person Responsible: Radiology Department Administrator</p> <p>Date Completed: 10/2010: Radiology staff educated on the Directive 10/2010 10/2010: Directive was approved by Chief of Radiology 10/15/2010 10/15/2010: Directive was approved by the Pharmacy and Therapeutics Committee 1/28/2011 1/28/2011: Directive was approved by the Executive Committee</p>	<p>10/2010</p> <p>10/2010</p> <p>10/15/2010</p> <p>1/28/2011</p>

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	<p>The Medication Administration Record (MAR) showed the patient received alteplase 56.94 mg (milligram) intravenously on [REDACTED]10 from 1615 hours to 1735 hours, as ordered.</p> <p>The CT scan of head dated [REDACTED]10 at 1925 hours, showed no evidence of intracranial hemorrhage. Diffuse atrophy (narrowing) and chronic small vessel (blood vessels) ischemic (blockage) disease was noted.</p> <p>The Multi-Discipline Progress Note dated [REDACTED]10 at 1925 hours, showed the patient was transferred to the Anaheim campus of the hospital for a cerebral (brain) angiogram (a fluroscopic test to take pictures of the blood flow in an artery or a vein) procedure. At 2129 hours, the patient had a cerebral angiogram procedure with blood clot retrieval procedure that was completed at 2152 hours. The cerebral angiogram report showed the patient had occlusion (blockage) of the right internal carotid artery (major paired artery, one on each side of the head and neck).</p> <p>The MAR showed the patient received the heparin bolus (whole) dose of 7,000 units on [REDACTED]10 at 2145 hours, as ordered, during the cerebral angiogram procedure, which was 4 hours and 10 minutes after the patient had received the alteplase medication.</p> <p>The MAR also showed the patient received continuous heparin intravenous infusion 25,000 units at 17 ml (milliliter) per hour from [REDACTED]10 at 2334 hours till [REDACTED]10 at 0030 hours, as ordered.</p>		<p>3. Action Plan: The Electronic Medical Record was enhanced to have a systemic pharmaceutical flag for a 24 hour look back for tPA administration to alert Practitioners and Staff (If heparin is ordered there will be a look back for 24 hours to see if tPA has been ordered and or hanging - which will then trigger the HC alert / Pharmaceutical flag.)</p> <p>Interventional Radiology Physician staff communication on electronic medical record enhanced to have a systemic pharmaceutical flag for 24 hour look back for tPA administration.</p> <p>Person Responsible: Regional Pharmacy Clinical Content Team</p> <p>Date Completed: 11/2010</p>	11/2010

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	<p>The Multi-Discipline Progress Note dated [REDACTED] 10, showed at "0000" hours, the patient had coffee-ground emesis (vomitus) and blood spurting from his right groin (the depression or fold where the legs join the abdomen) where there was an arterial (blood vessel) puncture from the earlier cerebral angiogram procedure. At 0030 hours, the continuous heparin infusion was discontinued. The patient was assessed to be nonresponsive with pupils unequal and sluggishly reacted to light, measuring 4 mm (millimeter) on the right pupil and 2 mm on the left pupil (normal = pupils equal, round, reactive to light). The right groin bleeding had stopped after 40 minutes of direct pressure applied. At 0400 hours, the patient had massive bleeding from the right groin again.</p> <p>The CT scan of head dated [REDACTED] 10 at 0356 hours, showed large hemorrhage areas were found in the right temporal (right side of the brain), right parietal (behind the frontal lobes of the brain), and right frontal lobes (behind the forehead, front side of the brain).</p> <p>The APTT result dated [REDACTED] 10 at 0407 hours, showed the patient's APTT was greater than 150 seconds (reference range was 23-35 seconds). Elevated APTT showed the patient had prolonged bleeding.</p> <p>On [REDACTED] 10 at 0415 hours, the patient was given protamine (antidote) 25 mg intravenously to reverse the anticoagulation effects of heparin and cryoprecipitate (antidote) 4 units to reverse the</p>		<p>4. Action Plan: Warm Handoff Algorithm/Checklist during tPA administration developed to include:</p> <ul style="list-style-type: none"> Pharmacist will dispense and deliver Alteplase tPA to the Nurse caring for the patient along with the - <i>tPA Protocol Check List, NO HEPARIN sign and green armband labeled "DO NOT GIVE HEPARIN"</i> Pharmacist and nursing, together at the bedside, will identify the patient using two identifiers per policy Pharmacist will apply the green armband to the patient on the same arm that the patient's admission armband has been placed The armband label will state: "DO NOT GIVE HEPARIN" Nursing will complete, in the presence of Pharmacist, the "No Heparin" sign and will place the sign above the patient's head of bed The signage will include the start date and time of the tPA infusion When completed, both nursing and Pharmacist will sign off on the tPA Protocol Check List <p>Pharmacy staff educated on Warm Handoff Algorithm during tPA administration Nursing staff educated on Warm Handoff Algorithm during tPA administration Radiology Nursing Staff educated on Warm Handoff Algorithm during tPA administration Radiology Physician staff educated on Warm Handoff Algorithm during tPA administration Neurology Physician staff educated on Warm Handoff Algorithm during tPA administration</p>	

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	<p>anticoagulation effects from the alteplase. At 0440 hours, the patient received one unit of platelets (small blood components) to help with blood clotting process and two units of red blood cells (blood component that contains hemoglobin) to supplement blood loss. At 1253 hours, the patient's heart rate had decreased quickly to asystole (a state of no cardiac electrical activity) and blood pressure was not detected. The physician pronounced the patient's death at this time.</p> <p>The hospital's Death Summary (Discharge Summary) report dated [REDACTED] 10 at 1514 hours, showed Patient 1 was admitted for stroke, received alteplase, was transferred from the Irvine campus to the Anaheim campus for the angiogram procedure, had prior CT scan of the head showing no intracranial hemorrhage, received heparin bolus and continuous infusion during and post the angiogram procedure, was found with a large volume of blood loss from the right groin, was given antidotes to reverse the anticoagulation effects of heparin and alteplase, was transfused with 2 units of blood, became comatose with pupils fixed and dilated, and had a stat (immediate) CT scan of the head showing extensive right hemispheric (half of the brain) hemorrhage with the extension in to the ventricular system (a set of structures containing cerebrospinal fluid in the brain) with compression of the brainstem (the posterior part of the brain).</p> <p>The Certificate of Death showed the patient expired on [REDACTED] 10 at 1253 hours, due to the immediate cause of spontaneous cerebral hemorrhage.</p>		<p>Action Plan #4 Continued:</p> <p>Person Responsible: Inpatient Pharmacy Directors, Chief Nurse Executives, Physician Chief of Neurology, Radiology Department Administrator</p> <p>Date Completed: 10/2010</p> <p>Measure of Success:</p> <ul style="list-style-type: none"> 100% checklist audit of all patients receiving tPA (according to the Warm Handoff Algorithm) completed by Pharmacy X 4months to achieve 100% compliance. 	10/2010

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	<p>On 10/12/10 at 0947 hours, in an interview with the DOP (Director of Pharmacy), he stated Patient 1 was admitted to the hospital on [REDACTED]10 at 2118 hours, with symptoms of stroke. The patient had received alteplase intravenously on [REDACTED]10 at 1735 hours. The patient's symptoms did not improve after the alteplase administration. The patient had a cerebral angiogram procedure and underwent a procedure to remove the clots. During the cerebral angiogram procedure in the Interventional Radiology (a medical sub-specialty of radiology which utilizes minimally-invasive image-guided procedures to diagnose and treat diseases in nearly every organ system) on [REDACTED]10, MD 1 (radiologist) had ordered to administer heparin 7,000 units as a bolus dose to Patient 1 at 2145 hours, after the patient had received the alteplase medication 4 hours and 10 minutes earlier. Then MD 1 ordered to administer continuous heparin intravenous infusion from [REDACTED]10 at 2334 hours till [REDACTED]10 at 0030 hours.</p> <p>On 10/12/10 at 1135 hours, during an interview, RN 1 stated Patient 1 received alteplase on [REDACTED]10 at 1735 hours, and then received bolus dose of heparin 7,000 units at 2145 hours. Heparin was administered 4 hours and 10 minutes after the administration of alteplase.</p> <p>On 10/12/10 at 1201 hours, the DOP (Director of Pharmacy) stated the APTT control is 30 seconds for a clot to form. When a patient is treated with heparin, the goal is 1.5-3 times the control or 45-90 seconds. Levels above 90 seconds indicate the blood was too thin, and there was increased risk of</p>				

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	<p>bleeding. The DOP stated on [REDACTED] 0 at 0407 hours, Patient 1's APTT result before his death was greater than 150 seconds.</p> <p>On 10/12/10 at 1330 hours, during an interview, MD 1 (radiologist) stated Patient 1 had total blockage of his right carotid artery. Present at the interview was the Director of Imaging Services. MD 1 stated he had performed the cerebral angiogram procedure to remove Patient 1's clots and written the orders for 7,000 units of heparin to be given by intravenous bolus and then continuous heparin infusion. MD 1 stated he did not follow the heparin protocol when he ordered the heparin and wanted to be aggressive with the heparin therapy to prevent the clots from returning. He stated he was aware that Patient 1 had received the alteplase medication 4 hours and 10 minutes earlier, but he wanted to administer the heparin medication to the patient anyway.</p> <p>The hospital's failure to follow their P&P on the administration of heparin not to be given to Patient 1 within 24 hours following the administration of alteplase 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).</p> <p>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 1280.1(c).</p>			

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