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<th>STATEMENT OF DEFICIENCIES</th>
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<td>E 000</td>
<td>Initial Comments</td>
<td>The following reflects the findings of the Department of Public Health during the investigation of an entity reported incident.</td>
<td>E 000</td>
<td>Preparation and execution of this plan of correction does not constitute admission or agreement by the provider of the truth of the facts alleged or conclusions set forth on the Statement of Deficiencies. This plan of correction is prepared and executed solely because it is required by federal/state law.</td>
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<td>E 264</td>
<td>Actions Taken:</td>
<td>1. Nursing Leadership reviewed the Physician's Order and Medication Administration Record policies and procedures.</td>
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<td>2. As of May 5, 2010, Nursing Leadership inserviced nursing staff on the Physician's Order and Medication Administration Record policies and procedures, emphasizing the process for verification of the</td>
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howver five doses of 150 mg IV were administered by a registered nurse. The facility's failure resulted in Patient sustaining sudden kidney failure, a seizure, and requiring continuous renal replacement therapy and hemodialysis.

Findings:

On April 6, 2010 at 10 a.m., an unannounced investigation of an acuity reported adverse event was conducted at the facility.

On April 5, 2010, a review of an Admission Face sheet, indicated Patient 1 was admitted to the facility on February 1, 2010 with the diagnosis of Cystic fibrosis exacerbation. According to the Cystic Fibrosis Foundation the condition causes the body to produce unusually thick, sticky mucus that clogs the lungs and leads to life-threatening lung infections.

A review of a History and Physical assessment conducted by a physician, dated February 1, 2010, indicated Patient 1 was admitted to the facility with bleeding of a port-a-cath (a device implanted in the body for long term intravenous antibiotic use) site and treatment of a lung infection.

On April 5, 2010, a review of a laboratory result report dated February 1, 2010 at 8:05 p.m. indicated Patient 1's Blood Urea Nitrogen (BUN) level was 20 milligrams/dL (mg/dL) and the Creatinine (Cr) level was 0.9 mg/dL (normal values: BUN 6-20 mg/dL and Cr 0.5-1.0 mg/dL). Urea is a byproduct secreted by the liver and removed from the blood by the kidneys. Creatinine is a byproduct of creatine found in a person's bloodstream that is removed by the body.
Kidneys. If kidney function is abnormal, the BUN and Creatinine levels will increase in the blood.

A review of a Physician's Order dated February 3, 2010 at 8:20 p.m. indicated to administer Colistin 100 mg IV every eight hours. The order was signed by Employee A.

On April 5, 2010 at 11:45 a.m. Employee B (director of pharmacy services) stated the pharmacist received the order for Colistin 100 mg IV every eight hours and input the order in the pharmacy's computer system. Employee B stated the pharmacist did not input the correct dose of Colistin and instead entered 150 mg IV every eight hours (50 mg more per dose than the physician ordered dose). According to Employee B, the medication input system "autopopulates" the dosage for Colistin as 150 mg.

On April 5, 2010 at 12:16 p.m., Employee B stated the pharmacist did not change the autopopulated dosage of Colistin to the correct ordered dose. Employee B stated that it was common practice for a pharmacist to create a Therapeutic Drug Monitoring Worksheet when a patient was to receive Colistin due to its potential risk for kidney toxicity. According to Employee B, the worksheet served as a tool to ensure that monitoring of patients was conducted while on Colistin; however, the pharmacist did not create a "Therapeutic Drug Monitoring Worksheet" for Patient 1.

On April 5, 2010 at 12:45 p.m., during an interview, Employee A (registered nurse) stated she received and signed the physician order for Colistin 100 mg IV every eight hours. Employee A stated she scanned the Colistin order into the pharmacy computer system to be prepared by medicating orders, including, but not limited to, the inputting of medication orders, performance of daily drug profile checks, and use of the therapeutic drug worksheet. Annual pharmacy competencies include processing and verification of medication orders.

Compliance and Monitoring Process:

1. Beginning September 1, the Director of Nursing or designee shall conduct random daily audits of Initial Physician Medication Orders and 24 Hour Chart Checks for 30 patient medical charts a day for one month and then 30 patient medical charts a month for 6 months to monitor nursing compliance. The Director of Nursing or designee shall take corrective action as necessary and report on compliance quarterly to the Performance Improvement Committee and the Quality Committee of the Hospital Governing Board.

2. Beginning September 1, the Director of Pharmacy or designee(s) shall monitor pharmacists' activities to assess compliance.
whether they are completing their assigned duties which include monitoring of all patient profiles. The Director of Pharmacy’s designee(s) include up to 6 Clinical Coordinator Pharmacists, which are uninvolved in the inputting of patient medication orders, on duty daily to complete this required monitoring and initiation of drug monitoring profiles. The Director of Pharmacy or designee(s) will be assessing the pharmacists’ compliance with completion of their daily duties for 6 months. The Director of Pharmacy shall report on compliance every other month to the Medical Executive Committee (MEC), which will subsequently report to the Quality Committee of the Hospital Governing Board.

Persons Responsible:

Director of Nursing
Director of Pharmacy

On April 5, 2010 at 1:00 p.m., during an interview with the Audi变动, Employee B stated that Colistin was an antibiotic that was not used frequently. According to Employee B, Colistin was nephrotoxic (toxic to the kidneys). A review of the facility’s current Drug Reference information indicated that colistimethate (Colistin) was an antibiotic used to treat infections and was generally reserved for cases where less toxic or more effective antibiotics were not available. According to the Drug Reference, side effects included tingling of the extremities, shortness of breath, nausea, and vomiting.

On April 5, 2010 at 4:11 p.m., Employee B stated that Colistin was an antibiotic that was not used frequently. According to Employee B, Colistin was nephrotoxic (toxic to the kidneys). A review of the facility’s current Drug Reference information indicated that colistimethate (Colistin) was an antibiotic used to treat infections and was generally reserved for cases where less toxic or more effective antibiotics were not available. According to the Drug Reference, side effects included tingling of the extremities, shortness of breath, nausea, and vomiting.

On April 5, 2010 at 12:45 p.m., during an interview with Employee A, the medication’s label and the medication were checked against the Elecld Electronic Medication Administration Record (EMAR). According to Employee A, the medication’s labeled dose of Colistin 150 mg matched the EMAR’s documented dosage entered by the pharmacist. Employee A stated she did not verify the medication’s labeled dosage with the pharmacist’s order for accuracy. Employee A administered Colistin 60 mg, instead of 100 mg, to Patient 1.

On April 5, 2010, during an interview at 1 p.m., Employee C (medical surgical unit nurse manager) stated that the facility’s policy to verify a physician’s order against the EMAR and the medication to ensure dosage accuracy. Employee C stated that the night shift nurses would conduct a physician’s order and EMAR audit to ensure accuracy; however, according to Employee C, the night shift nurse overlooked the accuracy of the dosage when she conducted the audit.

On April 5, 2010 at 4:11 a.m., Employee B stated that Colistin was an antibiotic that was not used frequently. According to Employee B, Colistin was nephrotoxic (toxic to the kidneys). A review of the facility’s current Drug Reference information indicated that colistimethate (Colistin) was an antibiotic used to treat infections and was generally reserved for cases where less toxic or more effective antibiotics were not available. According to the Drug Reference, side effects included tingling of the extremities, shortness of breath, nausea, and vomiting.

On April 5, 2010 at 12:45 p.m., during an interview with Employee A, the medication’s label and the medication were checked against the Emed Electronic Medication Administration Record (EMAR). According to Employee A, the medication’s labeled dose of Colistin 150 mg matched the EMAR’s documented dosage entered by the pharmacist. Employee A stated she did not verify the medication’s labeled dosage with the pharmacist’s order for accuracy. Employee A administered Colistin 60 mg, instead of 100 mg, to Patient 1.

On April 5, 2010, during an interview at 1 p.m., Employee C (medical surgical unit nurse manager) stated that the facility’s policy to verify a physician’s order against the EMAR and the medication to ensure dosage accuracy. Employee C stated that the night shift nurses would conduct a physician’s order and EMAR audit to ensure accuracy; however, according to Employee C, the night shift nurse overlooked the accuracy of the dosage when she conducted the audit.

On April 5, 2010 at 4:11 a.m., Employee B stated that Colistin was an antibiotic that was not used frequently. According to Employee B, Colistin was nephrotoxic (toxic to the kidneys). A review of the facility’s current Drug Reference information indicated that colistimethate (Colistin) was an antibiotic used to treat infections and was generally reserved for cases where less toxic or more effective antibiotics were not available. According to the Drug Reference, side effects included tingling of the extremities, shortness of breath, nausea, and vomiting.
speech, paresthesias (numbness), confusion, and seizures. The Drug Reference information noted the renal side effects included increases in blood urea nitrogen (BUN), increases in creatinine, decreased urine output, and renal toxicity. According to the Drug Reference, the maximum dose should not exceed 8 mg per kilogram (kg) per day and should not exceed 300 mg per day.

On April 5, 2010 at 5:05 p.m., during an interview Employee D (registered nurse) stated she was the nurse that conducted the audit for Patient 1's Colistin order. Employee D stated she did not remember verifying the dose of Colistin that night. Employee D stated she was "busy doing many things." Employee D stated she signed the physician's order indicating that Colistin was verified for dosage accuracy on the EMAR during the nightly chart check; however, Employee D stated she cannot recall verifying the Colistin dosage for Patient 1.

On April 5, 2010, a review of an EMAR, indicated Patient 1 was administered Colistin 150 mg on February 3, 2010 at 8 p.m.; February 4, 2010 at 2 a.m., 10 a.m., 6 p.m., and February 5, 2010 at 2 a.m. According to the EMAR, the Colistin dose that was due on February 5, 2010 at 10 a.m. was held due to an abnormal kidney function laboratory result.

On April 5, 2010, a review of a physician's order dated February 5, 2010 at 3:30 p.m., indicated to discontinue the use of Colistin for Patient 1.

According to the Patient Care Flowsheet dated February 5, 2010 at 8 p.m., Patient 1 was oliguria (decreased production of urine which may be a sign of kidney failure).
A review of a Patient Care Flowsheet dated February 6, 2010 at 12:30 a.m., indicated that Patient 1 stated she has had decreased urine output since February 4, 2010.

A review of a Critical Care Flowsheet, dated February 7, 2010 at 1:30 a.m., indicated Patient 1's urine output was low and the patient's physician was notified. According to the flowsheet, Patient 1 was placed on a continuous intravenous infusion of Bumex (a potent medication used to increase urine production) and after two hours of the infusion the patient had "little to no improvement in urine output."

On April 5, 2010, a review of a laboratory result report dated February 7, 2010, indicated Patient 1's BUN was 75 mg/dL and the Cr was 7.4 mg/dL (normal values: BUN 6-20 mg/dL and Cr 0.5-1.0 mg/dL).

A review of a Critical Care Flowsheet, dated February 7, 2010 at 7:30 a.m., indicated the nephrology team was talking to the patient regarding Continuous Renal Replacement Therapy (CRRT). CRRT, is a slow continuous therapy where a patient's blood is passed through a set of tubing via a machine where waste products (creatinine and urea) and water was filtered and removed when the kidneys are in failure. At 1:20 p.m., a catheter was placed in Patient 1 for initiation of CRRT to treat the renal failure.

On April 5, 2010, a review of a Progress Note indicated Patient 1 was examined by a nephrologist on February 7, 2010 at 8:30 a.m. According to the renal consult note, the patient was administered the wrong dose of Colitam and...
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the Cr laboratory result was elevated. According to the flowsheet, the patient sustained acute (sudden) renal failure after Colistin was administered. The note indicated that Colistin toxicity could cause neuromuscular blockade and renal failure.

A review of an attending renal physician note, dated February 7, 2010, indicated Patient 1 had Colistin induced toxicity and the patient was in acute renal failure and would require hemodialysis (a method for removing waste products such as creatinine and urea as well as free water from the blood when the kidneys are in failure).

On April 5, 2010 a review of a Continuous Renal Replacement Therapy Physician Order dated February 7, 2010 at 10 a.m., indicated to start CRRT therapy for Patient 1. A review of a CRRT Flow Sheet indicated CRRT therapy was initiated on February 7, 2010 at 3:30 p.m. Patient 1 underwent CRRT therapy for approximately 70 hours.

A review of a Critical Care Flow Sheet, dated February 7, 2010 at 3:20 p.m., indicated Patient 1 was not responsive to verbal stimulus.

A review of a Critical Care Flow Sheet, dated February 8, 2010 at 3 a.m., indicated Patient 1 was not able to follow commands and had a "blank stare." At 12 p.m., according to the Critical Care Flowsheet, the patient was monitored with an electroencephalograph (used to assess and diagnose abnormalities of brain function via electrocatalyst activity) machine and was found to have seized activity.

A review of an electroencephalograph (EEG)
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On April 5, 2010, a review of a Consultation Report conducted by a neurologist (brain physician) dated February 8, 2010 at 3:46 p.m. indicated Patient 1 had Colistin 100 mg ordered by a physician; however "Colistin was mistakenly given [at] 150 mg." According to the report on February 5, 2010 Patient 1's renal function started to deteriorate and required CRRT for treatment of renal failure. The Consultation Report indicated Patient 1 reported tingling sensation in both hands in the morning of February 6, 2010 and by the evening was unable to verbally communicate. According to the report, Patient 1 developed acute encephalopathy (brain dysfunction) related to the metabolic disturbances caused by the patient's renal failure. A review of the report indicated the renal failure was likely caused by the high doses of Colistin.

On April 9, 2010, a review of a Nephrology (kidney) Daily Progress Note dated February 8, 2010, indicated that Patient 1 sustained "acute renal failure due to Colistin."

On February 10, 2010 CRRT was discontinued at 2 p.m. and hemodialysis was initiated.

On April 9, 2010, a review of Acute Hemodialysis Flowsheet indicated Patient 1 received hemodialysis on February 11, 12, 15, 16, 19, 20, 22, 25, and 26, 2010; and March 12, 13, 15, 17, 18, 20, 23, and 29, 2010.

A review of a laboratory result report dated April 5, 2010 indicated Patient 1's BUN was 53 mg/dl, and the Cr returned to baseline level and was 0.7.
A review of the facility's policy and procedure titled "Physician's Orders" dated June 28, 2005 indicated the night shift nurse would conduct a chart check to ensure accuracy of transcription and prevention of errors. The policy stipulated that pharmacy would deliver the medication with the name of the medication on the label and the nurse would verify the label with the computer to ensure the medication entry by pharmacy was accurate. The facility's Physician's Orders policy stipulated the nurse would verify new medications orders by checking the original physician order prior to carrying out the order; however according to employee A, the Colistin order was not verified with the original physician's order prior to its administration to Patient 1.

The facility's failure to implement its policies and procedures to ensure a patient received the proper dose of medication, as ordered by the physician, 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 1560.1.