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CHI ST LUKE'S HEALTH BAYLOR COLLEGE OF MEDICINE ME	6720 BERTNER HOUSTON, TX 77030

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A 000	INITIAL COMMENTS	A 000		

The Centers for Medicare and Medicaid Services in conjunction with the State of Texas Department of Health and Human Services conducted a complaint survey at CHI ST. Luke's Health Baylor College of Medicine Medical Center. The survey dates were from January 7, 2019 to January 11, 2019.

The hospital census on January 7, 2019 was 543.

This report contains the deficiencies related to the complaint intake number 181344022.

The following Hospital Condition of Participation were deemed out of compliance:

42 CFR 482.21 Quality Assessment & Performance Improvement

42 CFR 482.23 Nursing Service

42 CFR 482.13 Patient Rights

Abbreviations:

ACMO Acting Chief Medical Officer
BP Blood Pressure
CCU Coronary Care Unit
CEO Chief Executive Officer
CNO Chief Nurse Officer
CT Computed Tomography scan
DIC Disseminated Intravascular Coagulopathy
ED Emergency Department
EGD Esophagogastro-duodenoscopy
EMR Electronic Medical Record
EVS Environmental Service

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

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F Fahrenheit
FFP Fresh Frozen Plasma
ICU Intensive Care Unit
IV Intravenous line
Lab Laboratory Department
MD Medical Doctor
MICU Medical Intensive Care Unit
QAPI Quality Assurance and Performance Improvement
PCA Patient Care Assistant
PLT Platelets
PRBCs Packed Red Blood Cells
RBC Red Blood Cells
RR Respiratory Rate
RN Registered Nurse
SAH Subarachnoid Hemorrhage
SPO2 Pulse Oximetry
Temp Temperature

Acetabulum:The socket of the hipbone, into which the head of the femur fits.

Anemia: A deficiency in the oxygen-carrying component of the blood, as in the amount of hemoglobin or the number or volume of red blood cells.

Arterial line: An arterial line is a thin catheter inserted into an artery.

Central venous catheter: A central venous catheter, also known as a central line, central venous line, or central venous access catheter, is

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a catheter placed into a large vein. Catheters can be placed in veins in the neck, chest, groin, or through veins in the arms. It is used to administer medication or fluids that are unable to be taken by mouth.

Cirrhosis: chronic disease of the liver marked by degeneration of cells, inflammation, and fibrous thickening of tissue.

Encephalopathy: Disease, damage, or malfunction of the brain. In general, encephalopathy is manifested by an altered mental state that is sometimes accompanied by physical changes.

Gastrointestinal: Relating to the stomach and the intestines.

Hemodialysis: Hemodialysis, or simply dialysis, is a process of purifying the blood of a person whose kidneys are not working normally by a machine.

Hypotension: Low blood pressure.

ORIF: Open reduction and internal fixation.

Plasma: the liquid part of blood or lymph.

Pulse: The rhythmic dilation of an artery that results from beating of the heart.
Pulse is often measured by feeling the arteries of the wrist or neck.

Shock index: The shock index (SI), defined as heart rate divided by systolic blood pressure, is an accurate diagnostic measure. Under normal conditions, a number between 0.5 and 0.8 is

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A 000	Continued From page 3 typically seen. SpO2: Blood oxygen saturation level. Tracheostomy: The surgical formation of an opening into the trachea through the neck especially to allow the passage of air. Ventilator: Ventilators are machines that support breathing. They get oxygen into the lungs, remove carbon dioxide from the body, help people breathe easier.	A 000		
A 115	PATIENT RIGHTS CFR(s): 482.13 A hospital must protect and promote each patient's rights. This CONDITION is not met as evidenced by: Based on records review and interviews, the hospital failed to administer blood products to patients in a safe manner. As a result, a Patient #27 received the incorrect blood type and died. The hospital failed to do the following in preventing the blood transfusion fatality: 1. The Emergency Department (ED) obtained blood from a patient with no physician order and failed to discard excess blood vials. 2. After the patient was discharged, Environmental Services (EVS) failed to notify the ED a blood specimen was left in the room. ED staff failed to check room for bodily fluids after patient was discharged. 3. The ED nurse failed to correctly label a blood specimen. This resulted in a blood specimen with	A 115		

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A 115	Continued From page 4	A 115		

two different patient labels (double labeled).

4. The laboratory department failed to reject the double labeled blood specimen received from ED.

5. The inpatient clinical staff failed to recognize possible signs and symptoms of blood transfusion adverse reaction.

6. The nursing staff failed to check vital signs during a blood transfusion per policy and procedure.

Records review indicated the following findings:

Patient #27 was a 75 year old female with a history of recent multiple falls, hypertension, and diabetes. She came to the facility's ED on [redacted], at 11:42 AM for altered mental status. A computed tomography (CT) revealed the patient had bleeding into the space surrounding the brain. Additional diagnoses included acute encephalopathy, severe sepsis, anemia, coagulopathy, and an acute kidney injury.

After consultations with a neurosurgeon, neurologist, and intensivist, the providers decided Patient #27 did not need surgical intervention for brain hemorrhage and patient will be admitted to an intensive care unit. Physician recommended treating the patient's anemia with a packed red blood cell (PRBC's) transfusion and treating the coagulopathy with a fresh frozen plasma (FFP) transfusion.

At 4:59 PM, while Patient #27 was still in the ED,

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A 115	Continued From page 5 a type and screen was ordered. The blood was received and accepted to laboratory department (lab) at 5:10 PM from the ED. At 5:44 PM Patient #27 was transferred to the Medical Intensive Care Unit (MICU). On [redacted], the patient received a FFP transfusion from 8:54 PM to 11:15 PM. At 11:15 PM, when the FFP transfusion was completed, the systolic blood pressure was noted to be 48 points lower than initial systolic Blood Pressure- from 158/80 to 110/55. On [redacted], a midnight assessment completed by RN #47 documented "blood in the urine." This is the first documentation of blood in Patient #27's urine since her visit at hospital. On [redacted], at 1:10 AM., RN #47 documented the following: "Provider notification: change in status hematuria Resident #1 notified by telephone; resident at bedside; no new orders." Patient #27 received the PRBC's transfusion on [redacted], from 1:17 AM to 0410 AM. At 4:10 AM, upon completion of the PRBC transfusion, RN #47 documented a blood pressure of 60/45 for patient #27. This was the first low blood pressure documented. RN#47 notified resident on call. A blood transfusion reaction was suspected and investigation started.	A 115		

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A 115	Continued From page 6 On [redacted], at 4:24 AM, the Laboratory director noted the following: "ABO incompatible transfusion reaction- Disseminated Intravacular Coagulation (DIC) and hypotension followed. Transfusing ABO-compatible products." Patient #27 blood type was B+, the Fresh frozen Plasma (FFP) and PRBC's that was transfused was A+. Physician notes indicated that Patient #27 became critically ill and required various interventions in an attempt to stabilize the patient. This included 30 units of various blood products transfused, intravenous medications to stabilize, multiple invasive lines insertion including intubation (inserting endotracheal tube from mouth to trachea to maintain and assist with breathing), additional physician consults, additional blood lab testing, and various further testing. Physician notes states CT of the brain was completed on Patient #27 on [redacted], at 10:30 AM. Results revealed "increased/new bilateral subarachnoid hemorrhage". Patient #27 had a total of four cardiac arrests with advanced cardiac life support on [redacted], over a three hour timeframe. The family decided to withdraw care after the fourth cardiac arrest. Patient #27 expired [redacted], at 12:50 PM. 1. The Emergency Department (ED) obtained blood from a patient with no physician order and failed to discard excess blood vials. Finding	A 115		

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A 115	Continued From page 7 include: A Root Cause Analysis (RCA) was initiated by the hospital after the death of Patient #27 (the RCA was ongoing at time of survey). The RCA documented the initial type and screen that was sent from the ED to the lab was not Patient #27 blood, but patient #28 blood specimen. Patient #28 was in ED room XX and admitted to an inpatient unit at hospital on [redacted]. Patient #27 was the next patient admitted to room XX in the ED. Record review on [redacted] indicated that Patient #28 did not have an order for a type and screen while in the ED. The Director of the Emergency Department and Director of Risk Management were interviewed on [redacted]. According to the interview, prior to the death of Patient #27, it was a normal practice to draw a "rainbow" (the practice of drawing extra vials of blood without a physician order) of blood work. The ED nurse would wait for the orders and use the blood that was already drawn to send. Records review showed the hospital had no policy or procedure for drawing "rainbow" blood tubes. During an interview with the ED Director, CNO and The Training/Education & Research Director on [redacted], all acknowledged the ED practiced drawing rainbow blood tubes prior to the death of Patient #27. 2. After the Patient #28 was discharged, Environmental Services (EVS) failed to notify the ED that a blood specimen was left in the room. ED staff failed to check room for bodily fluids after patient was discharged. Findings include:	A 115		

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A 115	Continued From page 8 During an interview with the ED Director and Risk Manager on January 8, 2019, it was asked who is responsible for checking the room for body fluids after a patient is discharged. When a patient is discharged it is the nurse or patient care assistant (PCA) responsibility to remove all bodily fluids in the room prior to environmental services (EVS) cleaning the room. EVS will not remove bodily fluids from a patient room. During an interview on January 8, 2019, at 9:54 AM, the EVS Director was asked what the responsibilities were for the EVS technicians in the emergency department. EVS director said the EVS staff clean counter tops, cabinets, stretchers, high dust the rooms, and sanitize all surfaces. EVS Director was asked what the responsibilities were for EVS staff when they found specimens of blood, bodily fluids in the room. EVS director said they are to stop and notify the nurse. EVS staff will not clean the room until the nurse removes the blood/urine specimens. EVS said all staff had been trained on the "New" protocol about a month ago. EVS director was asked to provide documentation of the training conducted with EVS staff. The EVS Director provided a document dated [redacted], which was prior to the incident that occurred in [redacted] involving Patient #27. No documentation was provided on staff training/education for cleaning patient rooms in the emergency department. One blood vial was left in ED room xx after patient #28 was discharged. As a result of the ED	A 115		

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room not being checked for bodily fluids by appropriate staff, the blood specimen stayed in the room for over 10.5 hours and was still in the room at the time patient #27 was admitted.

The ED nurse failed to correctly label a blood specimen. This resulted in a blood specimen with two different patient labels (double labeled). Findings include:

A Root Cause Analysis (RCA) was initiated by the hospital after the death of Patient #27 (the RCA was ongoing at time of survey). The RCA documented the initial type and screen that was sent from the ED to the lab was not Patient #27 blood sample, but Patient #28 blood sample. The RCA noted while Patient #27 was in the ED, a type and cross was ordered. The specimen tube in the ED room already had a patient label on it. A second label was placed over the blood (patient #27 label) and sent to lab.

CHI St. Luke Health Policy and Procedure-Specimen Identification, Collection and Transportation-Pathology that was effective July 2017 states: "Specimen Collection and Labeling Process ....ii Collect the appropriate specimen(s) and place one label on the primary container in the presence of the patient."

The policy also stated, for transfusion service specimens the only two acceptable labels are "epic specimen label or a handwritten label".

An interview was conducted with the Training/Education & Research Director on January 8, 2019. The Director of Education

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stated applying multiple patient labels on specimens was a "bad practice" and "sloppy practice". the Director of Education also stated multiple labels on a lab specimen was a safety issue.

The lab department failed to reject the double labeled blood specimen received from ED. Findings include:

CHI St. Luke Health Policy and Procedure-Specimen Identification, Collection and Transportation-Pathology that was effective July 2017 states: "Specimen Collection and Labeling Process ....ii Collect the appropriate specimen(s) and place one label on the primary container in the presence of the patient."

The policy also stated for transfusion service specimens the only two acceptable labels are "epic specimen label or a handwritten label".

Audit reports from July 2018 to January 2019, showed the lab rejecting lab specimens with multiple labels on tubes.

On January 10, 2019, at 5:00 PM, the hospital CEO was interviewed concerning the pattern of mislabels on blood tubes to be type and screen. The CEO stated, it should be zero. "This are patients life and blood is important". The CEO stated that they will have to retrain all the nurses to ensure that there are no mislabels of blood sample tubes. The CEO stated, "This is unacceptable".

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The inpatient staff failed to recognize possible signs and symptoms of blood transfusion reaction. Nursing staff failed to check vital signs during a blood transfusion per policy and procedure. Findings include:

CHI St. Luke health Transfusion of Blood Products-Patient Care states the following:

"Check vital signs 15 minutes after making any connection. (Initial vital sings must be within the previous 15 minutes)"

"Monitor vital signs and assess temperature and urine throughout the transfusion process to monitor for adverse reactions to blood products and the effectiveness of treatment. Vital signs are done every hour, and when the transfusion is complete."

"Monitor for signs and symptoms of transfusion reactions."

"Symptoms of a transfusion reaction .....

iv. Increase or decrease in blood pressure of more than 20mmHg ....

xi. Hypoxemia (change in oxygen saturation of greater than 5% or any decrease to less than 90%) .....

xiv. Hematuria/dark urine"

"In a suspected transfusion reaction, IMMEDIATELY:

i. Stop transfusion and maintain patency of

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IV line ... .

vii. Notify transfusion Service and physician. Notification of Transfusion Service must be within 15 minutes of reaction."

During Patient #27's FFP transfusion the following vital signs were not documented:

On [redacted], at 10:00 PM hourly and 11:00PM hourly no temperature.

On [redacted], at 10:00 PM hourly pulse.

On [redacted], at 11:00 PM hourly blood pressure.

During Patient #27's PRBC transfusion the following vital signs were not documented:

On [redacted], at 2:00 AM hourly, 3:00 AM hourly and 4:00 AM hourly Temperature.

On [redacted], at 4:00 AM hourly Pulse.

On [redacted], at 2:00 AM hourly, 3:00 AM hourly and 4:00 AM hourly Blood Pressure.

On January 9, 2019, RN #47 was interviewed. This nurse verified she was assigned to Patient #27 on [redacted], during 7:00 PM-[redacted] 7:00AM. When assessed at the beginning of shift (7 PM) Patient #27 was alert and oriented with occasional confusion and was not on supplemental oxygen. RN #47 also confirmed she administered the FFP and PRBC's

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A 115	Continued From page 13 to Patient #27. This nurse verbalized, she noticed a change in the color of urine around midnight [redacted], and notified the resident on-call (Resident #1). The resident decided to continue monitoring patient. RN #47 said the next change in condition was toward the end of PRBC transfusion when the BP was 60/45, RN #47 notified physician and blood transfusion reaction was suspected. RN #47 acknowledged all vital signs were not completed per policy during blood products transfusion.	A 115		
A 263	QAPI CFR(s): 482.21 The hospital must develop, implement and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program. The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS. This CONDITION is not met as evidenced by: Based on interview and record review, the hospital Quality Assurance and Performance Improvement (QAPI) Program failed to ensure	A 263		

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A 263	Continued From page 14 the measuring and analyzing of adverse events, and occurrences. QAPI also failed to implement corrective actions for reports reviewed from October 2017 - January 2019. The focus of this survey was based on a blood transfusion adverse event involving laboratory services, blood bank, environmental services, and nursing services. Findings: 1. Patient #27 received the wrong blood type on [redacted], as a result of mislabeling of blood specimens by facility staff. 2. Patient #27 had a transfusion reaction, developed severe complications, and died. The hospital failed to ensure occurrences involving mislabeling were addressed and corrective actions implemented prior to and after the [redacted], incident. 3. The facility failed to ensure the identified concerns with nursing services recognition of transfusion reactions were addressed and corrective actions implemented. 4. The hospital failed to ensure information received about nursing services having problems with the electronic charting transfusion documentation were addressed and corrective actions implemented. The facility was tracking the problems, but failed to trend so corrective actions could be implemented and monitor. This deficient practice had the likelihood to cause harm in all patients who had blood laboratory test drawn in the hospital.	A 263		

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A 263	Continued From page 15 Review of facility's occurrence reports and investigations revealed the following: From September 2018 - January 9, 2019, there were 122 incidents involving mislabeling or problems with labeling of blood (type and screen) laboratory specimens. Review of an Emergency Department (ED) occurrence dated [redacted], revealed the following: On [redacted], the blood bank received a request for 1 unit of packed red blood cells (PRBC's) and 1 unit of platelets on the wrong patient. The blood product ordered were missing a type and screen order (this test is used to determine the patient blood type). The ED was notified the blood products ordered was placed on the wrong patient and the type and screen order was missing. The incorrect order was canceled and the correct order was placed. There was no documentation as to what corrective action was implemented. Patient #51 and #52 were the involved in the incident. Review of an Emergency Department occurrence dated [redacted], revealed the following: "Patient developed severe hypotension at the end of PRBC (Packed Red Blood Cell) transfusion. Transfusion reaction panel sent. Reportedly type and screen had been mislabeled resulting in likely ABO (antibodies blood group) mismatch." Review of the hospital internal investigation revealed Patient #27 received the wrong blood	A 263		

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type transfusion on [redacted], as a result of mislabeling of blood specimens by hospital nursing staff. Patient #27 had a transfusion reaction, developed severe complications, and died.

Review of an ED occurrence dated [redacted], revealed the following:

A PRBC transfusion order for patient #59 in the ED was started documented on the electronic flowsheet (by RN #30) but product was not stopped nor completed in flowsheet. The patient was transferred to ICU (unit 7 South 2) around the time the blood product might have stopped.

Review of the ED record on patient #59 revealed, he had a potential blood transfusion reaction. patient #59's unit of blood was sent to the laboratory for investigation of a transfusion reaction.

This event was not documented in the occurrence information.

In January 2019, there were 21 incidents involving mislabeled tubes and 1 was doubled labeled.

During an interview on January 8, 2019, after 10:51 AM, the Quality Director reported that as a result of their investigation on Patient #27, they found the following problems:

1. A failure to follow their process for labeling in the ED.

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A 263	Continued From page 17 2. A failure to recognize changes of blood transfusions reactions in the Intensive Care Unit. The quality director reported the information about the new processes went to the clinical hospital staff on December 21, 2018, and were effective January 1, 2019. During an interview on January 9, 2019, after 2:55 PM, the Quality Director verbalized he was not notified about the potential transfusion reaction on Patient #59 which occurred on [redacted]. The quality director reported he "knew for sure" he did not have an incident report on Patient #59 and not all blood transfusion reaction incidents are reported to the quality program. During the same interview, the Quality Director stated "Every transfusion reaction did not result in a Root Cause Analysis (RCA). If it went to the transfusion services, they completed a form and they would refer it to clinical services and as needed for a RCA to review". When asked who was keeping up with nursing services ability to assess transfusion reactions the quality director reported an auditing tool was being developed today (January 9, 2019). The Quality Director provided the information for the incident dated [redacted], which revealed the incident was a near miss (an unplanned event that did not result in injury, illness or damage but had the potential to do so). There was no documentation as to what intervention was implemented to prevent this type of incident from occurring again.	A 263		

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The Quality Director was asked what was implemented after the November 28, 2018, incident. He reported the error was caught by the laboratory and it was a human error. The nurse entered the order in wrong patient medical record. The patient's physician was notified of the order error and the incident was not escalated to the medical staff.

During an interview on January 10, 2019, after 2:45 PM., the following was revealed:

The laboratory director reported responsibility for monitoring utilization of blood transfusions. He was not satisfied with the number of blood transfusions that were left open by nursing. The director stated, the laboratory was not responsible for monitoring the nurse's documentation. Nurse #37 is responsible for monitoring nursing documentation for blood transfusions. Nurse #37 sent out a daily email to the laboratory, nurse managers and transfusion services with the problems found.

The Laboratory Director reported that the chain of command for information sharing was from blood transfusion committee to quality of care. If it was up for peer review it went directly to the Medical Executive Committee. If not up for peer review it went to Quality, Medical Executive Committee and then to the Governing Body.

RN#37 reported that he kept up with the nursing portion of the audits and sends the audits out to the nursing departments daily. The audit included the number of transfusions records which were not closed. RN #37 reported he was not trending

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the numbers. They were in the process of developing a tool to trend several subjects including blood transfusion reactions.

RN#37 verbalized the quality director receives the daily audit report.

Review of the Transfusion Committee minutes revealed the following concerns involving blood specimens:

1. October 26, 2018:
"Staff Nurse Practice Professional Council is developing an educational plan to improve bar code identification. Recent incident of wrong blood in tube points to the need to improve performance. Mandatory nursing skills fair is planned on a quarterly basis."

2. January 25,2018:
"Turnover in nurses seems to be leading to ongoing problems with closure of transfusion events in Epic. Ongoing training will be needed."

3. July 2018
Two Quality Alert were sent out for the following:

"Improperly labeled samples.

Samples are being received in laboratory with labels affixed incorrectly.

Units are sending samples to Pathology with labels that are crooked or improperly positioned on the tube.

Labels not affixed straight on the tube are unable to be read on laboratory analyzers

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A 263	Continued From page 20 Samples must be re-labeled once received in lab, causing a delay in processing/analysis and potential for identification errors.." 4. "Barcode Label Printer Maintenance. Sample labels are being printed on dirty printers causing inferior label quality and readability." 5. Review of quality committee minutes from July -December 2018 revealed the following four performance improvement projects for the last six months; "Sepsis and epic Optimizations Universal Protocol VTE Risk Assessment EPIC Build Overview Improving Nutrition in the ICU." There was no project improvement in place to address nursing recognition of blood transfusion reactions. Review of the facility's Quality Manual 2018 "pages 5 and 6 revealed the following: "..The QMS (Quality Management System) program includes, but is not limited to the following: A focus on indicators related to improved health outcomes and reduction of adverse events. An ongoing process to demonstrate measurable improvement in indicators for which there is evidence of improved health outcomes and	A 263		

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A 263	Continued From page 21 reductions in adverse events: Measurement, monitoring, and analysis of quality and patient safety indicators, including adverse events, and other aspects of performance to assess processes of care, treatment, services, and operations provided; and Continual improvement of health outcomes and reducing risk for patients.."	A 263		
A 385	NURSING SERVICES CFR(s): 482.23 The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse. This CONDITION is not met as evidenced by: Based on observation, interview, and record review: 1. The hospital's nursing staff failed to monitor and document blood transfusions of patients in accordance with facility policy, medical record procedures, and current standards of practice. Vital signs of patients who received blood transfusions were not documented in accordance with facility policy (Patients: #5, #6, #12, #16. #17, #18, #19, #39, #29, #32, #35, #36, #40, #41, #43, #45, #51, #52, #56, #57, #59, #61, #65). 2. The "Single Blood Transfusion" patient event in the EMR (electronic medical record) was not consistently ended or completed at the end of the blood transfusion, which resulted in an inaccurate and incomplete patient record (Patients #41, #43, and #45).	A 385		

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The single blood transfusion record for Patient 43 was altered 2 days after a blood transfusion finished; the electronic record was not ended or completed (closed) at the end of the blood transfusion and was left opened. This resulted in an inaccurate and incomplete medical record (Patient #43). The volume of the blood product transfused was not consistently documented in the "Single Blood Transfusion" record (Patient #39, #41, and #42).

3. The hospital failed to ensure that blood or blood components for transfusions were transported in a safe manner. Staff that had not been trained were transporting blood and blood components from the blood bank to the patient unit. Nursing staff were unaware of which personnel, by title, could transport blood or blood components. There was no policy stating who could pick up blood products from the blood bank and there was no training on transporting blood products from the blood bank to the unit.

4. The hospital failed to ensure that nurses were able to monitor patients receiving blood transfusions in a safe manner. Nurses performing blood transfusion responsibilities did not know which alerts would be triggered by the EMR to indicate that a patient was having a possible transfusion reaction. Nurses interviewed stated that up to 5 vital signs indicators (temperature, pulse, respirations, blood pressure, and oxygen saturation) would alert in the EMR, when the system actually only alerted 2 vital signs indicators (temperature and oxygen saturation). This indicates that nurses have a lack of knowledge and training on the blood transfusion component of the EMR. This presents a risk that

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any patient having a blood transfusion could potentially have a serious transfusion reaction that would not be recognized emergently if a nurse was relying on the EMR for nonexistent alerts.

The findings present a likelihood that serious blood transfusion reactions may not be detected in an expeditious manner, which could delay appropriate response and treatment, and could result in death or injury to a patient. The findings also present a risk that an inaccurate or incomplete blood transfusion medical record could result in errors in patient diagnosis and treatment. The deficient practices had the potential to affect all patients receiving blood products at the hospital.

Findings included:

Review of patients who received blood transfusion:

Review of the facility policy titled, "Transfusion of Blood Products - Patient Care" dated May 2018 revealed the following:

"POLICY:

A. Prime with only 0.9% Sodium Chloride solution.

B. Check that no medication or other IV solutions are infusing with blood products ....

H. If the blood product component container is entered for any reason, the component will expire

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after 4 hours.

I. The blood product must be initiated immediately upon issue.

J. Transfusions should be completed within 4 hours and before the expiration date and time of the blood component ...

L. Transfusion reactions can be life threatening and occur with exposure to even a small amount of blood: therefore, transfusions should be started slowly unless the patient's condition requires a rapid, life sustaining transfusion. Baseline vital signs should be obtained within 60 minutes of initiation of the transfusion and should be reassessed at the end of the first 15 minutes, every hour and when the transfusion is complete.

M. All suspected transfusion reactions should be immediately reported to Transfusion services.

PROCEDURES: (NON-OPERATING ROOM AREA'S)

1. A physician's order is required for the transfusion of blood and blood products....

3. Assessment Before Transfusion:

a. Verify the correct patient using two patient identifiers (any two: name, medial record number, and/or date of birth ....

f. Assess vital signs, including blood pressure, heart rate, respiratory rate, oxygen saturation and temperature. (Initial vital signs must be within the previous 15 minutes)

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A 385	Continued From page 25 4. Administration a. Before initiating a blood or blood component transfusion: 1. Use a two-person verification process (two licensed staff) 2. Match the blood or blood component to the order 3. Match the patient to the blood or blood component 4. Verify blood product and patient match by checking blood bag tag, blood bag, and Patient identification band .... l. Check vital signs 15 minutes after making any connection. (Initial vital signs must be within the previous 15 minutes) o. After 15 minutes, if no signs of a transfusion reaction are noted, reassess vital signs and increase the flow rate to the desired speed. Infusion time should not exceed 4 hours .... p. Monitor vital signs and assess temperature and urine throughout the transfusion process to monitor for adverse reactions to blood products and the effectiveness of treatment. Vital signs are done every hour, and when the transfusion is complete .... 8. Transfusion Reaction a. Symptoms of a transfusion reaction. 1. Temperature elevation during transfusion	A 385		

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Greater than 1 degree Celsius or Greater than 2 degrees Fahrenheit

2. Chills/rigors

3. Tachycardia or bradycardia

4. Increase or decrease in blood pressure of more than 20 mmHG

5. Shock

6. Pain or burning at infusion site.

7. Chest pain or tightness

8. Back/Flank pain

9. Cough (New or increasing)

10. Shortness of breath or wheezing (Document all abnormal oxygen saturation

Measurements and treatments given when reporting a suspected reaction to transfusion Service).

11. Hypoxemia (Change in oxygen saturation greater than 5% or less than 90 %)

12. Flushed skin

13. Nausea/Vomiting

13. Hematuria/dark urine

14. Diffuse bleeding

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A 385	Continued From page 27 15. Urticaria/Hives b. In a suspected transfusion reaction, 1. IMMEDIATELY stop the transfusion and maintain patency of IV line. 2. Scan the patient armband. 3. Select blood product transfusing and select "STOP" IN TV-PDA. 6. Monitor vital signs 7. Notify transfusion service and physician. Notification of transfusion service must be within 15 minutes of reaction .... 9. Placed unused portion of blood product and tubing in a plastic bag ... 13. Complete transfusion reaction Investigation form. 14. Send to transfusion service within 60 minutes of symptom onset: 1. Blood bag and tubing 2. 6 ml pink top EDTA tube 3. Blood transfusion reaction investigation form Blood cultures if temperature elevation ..." Patient #5:	A 385		

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Patient #5 had a diagnosis of shortness of breath, coronary artery disease, abnormal stress test, angina pectoris, coronary artery bypass grafting, hypertension, hyperlipidemia and gastroesophageal reflux disease. The patient was 66 years old. On [redacted] a physician ordered 1 packed red blood cells (PRBC's) transfusion. The transfusion began at 4:20 PM. The electronic medical record (EMR) does not have a time when the transfusion was completed. This information was verified and validated by RN #52.

The pre-transfusion vital signs were taken at 4:15 PM: Temperature 98.6 F., Pulse 67, Respiration 24, Oxygen Saturation 92% and Blood Pressure 116/60.

No vital sign were documented at 4:45 PM.

At 5:00 PM: vital signs: Pulse 66, Respiration 20, Oxygen Saturation 98%. No Temperature or Blood Pressure were documented in the Blood Transfusion electronic template

At 5:18 PM: vital sign: Pulse 67, Respiration 28, Temperature 99.2 F.

At 6:00 PM: vital sign: Pulse 62, Respirations 13, no Blood Pressure or Temperature were recorded on the Blood Transfusion EMR.

At 7:00 PM: vital sign: Pulse is 81 and Respiration 32. No Temperature, Oxygen Saturation or Blood Pressure were documented on the Blood Transfusion EMR.

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A 385	Continued From page 29 Patient #6: Patient #6 had a diagnosis of pulmonary edema, congestive heart failure, type 2 diabetes mellitus, anemia, cardiogenic shock and sepsis shock. On [redacted], a physician ordered 1 PRBC transfusion. The transfusion was started on [redacted], at 1:11 AM and ended on [redacted], at 4:00 AM. EMR review indicated that the pre transfusion vital signs at 1:11 AM were: Temperature 97.6 F, Pulse 82, Respirations 16, Blood Pressure 110/46, and Oxygen Saturation 100%. At 1:23 AM (15 minutes after the blood transfusion started): only the Blood Pressure was taken 106/40. At 1:30 AM: vital signs were: Pulse 79, Respiration 19, and Oxygen Saturation 100%. No Temperature or Blood Pressure were documented. At 1:45 AM: vital sign: Pulse 79, Respiration 19, Oxygen Saturation 100%, and Blood Pressure 108/45. No Temperature was documented. At 2:00 AM: vital sign: Pulse 81, Respiration 16, Oxygen Saturation 100%. No Temperature was documented. At 2:03 AM: Blood Pressure 89/42, no Temperature, Pulse, or Oxygen Saturation was documented. At 2:15 AM: Pulse 90, Respiration 26 and Oxygen	A 385		

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Saturation 99%. No Blood Pressure was documented.

At 2:23 AM: Blood Pressure 89/41. No Pulse, Respiration, Temperature or Oxygen Saturation was documented.

At 2:45 AM: Blood Pressure 91/43, Pulse 81, Respirations 17, and Oxygen Saturation 100%. No Temperature was documented.

A 3:00 AM: Temperature 98.9 F. No Pulse, Blood Pressure, Oxygen Saturation, and Respirations were documented.

At 3:15 AM Pulse 84, Respiration 23, Oxygen Saturation 99%. No Blood Pressure was documented.

At 3:45 AM: Pulse 83, Respiration 20, Oxygen Saturation 100%, and Blood Pressure 116/40. No Temperature was documented.

The Blood Transfusion EMR is designed for the nurse to write a freestyle note as needed. However, no documentation was written on the template. There was no evidence that the nurse called the blood bank to notify changes on the patient vital signs, per hospital policy and procedure.

Patient #12:

Patient #12 had diagnosis of breast cancer and post breast lumpectomy. On [redacted], a physician ordered 1 PRBC transfusion at Kirby Glen Infusion Center

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A 385	Continued From page 31 The transfusion started on [redacted], at 11:31 AM and ended [redacted] at 1:42PM. At 11:06 AM, the pre-transfusion Blood Pressure was 130/54, Pulse 77, Respiration 20, Temperature 98.3 F, and Oxygen Saturation of 97%. Electronic Medical Record showed no vital signs were done 15 minutes after the transfussion was started. Vital Signs at 12:10 PM, Blood Pressure 116/63, Pulse 69, Respirations 16, Temperature 97.6 F, and Oxygen Saturation of 100% at two litters of oxygen. At 1:10 PM, Blood Pressure 128/59, Pulse 52, Respiration 18, Temperature 97.6 F, and Oxygen Saturation 100% at two litters of oxygen. It was confirmed that there are no RN notes indicating the change on patient pulse from 77/minutes pre transfusion to 52/minutes. At 1:42 PM, Blood Pressure 125/58, Pulse 58, Respiration 18, Temperature 97.9 F, and Oxygen Saturation 100 % at two litters of oxygen. Last set of vital sign were Blood Pressure 123/58, Pulse 55, Respirations 20, Temperature 97.9 F, Oxygen Saturation 100% at two litters of oxygen. After the last set of vital sign, the patient was discharged home. The nursing notes does not address the patient pre transfusion Pulse of 77/minute and it went as low as 55/minute. The nurse administered two litters of oxygen, however, there is no note on the Blood Transfusion template that addressed the patient low pulse after the transfusion was started. On January 10, 2019, at 2:15 PM, RN #52 was	A 385		

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A 385	Continued From page 32 interviewed. The RN stated that the RN should address the change in the patient pulse in the EMR during the transfusion. RN #52 validated the starting pulse was 77 beats per minute, the last documented pulse was 55 beats per minute and the patient was discharged home. RN #52 also confirmed that the blood bank was not notified about the pulse changes. Patient #29: Patient #29 received two units of platelet products at Kirby Glen Oncology Infusion Center [redacted], from 3:49pm - 4:54pm. One of the two units (the 2nd platelet transfusion) did not have vital signs documented at completion of transfusion at 4:54pm. Patient #32 Patient #32 received one unit of PRBC's [redacted], from 11:48 AM-2:40 PM on 11 tower unit. There was no vital signs documented at completion of transfusion at 2:40 PM. Patient #35 Patient #35 received one unit of FFP [redacted], on 22 tower unit from 7:43 AM.- 9:17 AM. There was no vital signs recorded 15 minutes within start time of transfusion. The first set of vital signs were documented 47 minutes after transfusion started.	A 385		

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A 385	Continued From page 33 Patient #36 Patient #36 received one unit of PRBC's [redacted], on 10 tower unit from 12:26 PM- 6:45 PM. The unit transfused for 6 hours and 19 minutes. Patient #36 also had no documentation of vital signs 15 minutes within start time of transfusion, at completion, and five of the six hours the blood was infusing. Patient #56: Review of the Daily Progress Notes for Hospitalist MD #9 on 8-2-2018 revealed the following: Patient #56 is a 53-year-old caucasian male with a past medical history significant for marfan syndrome, chronic kidney disease stage IV, type I aortic dissection and aortic valve repair. On [redacted], Patient #56 had a resection and replacement a thoracic abdominal aortic aneurysm. Review of the Blood Transfusion record for Patient #56 on [redacted], revealed the following: An order for Type and Screen, and transfuse one unit of PRBC was entered on [redacted], at 7:57 AM. The nurse listed on the blood transfusion record was RN #18. The second RN/verification signature was RN #19. The blood transfusion was started at 1:54 PM on [redacted], and stopped on [redacted],	A 385		

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A 385	Continued From page 34 at 2:30 PM. There was no documentation in the record at what time the blood product was picked up from the Blood bank. Vital signs on the blood transfusion record show: [redacted] At 1:30 PM - Blood Pressure 149/54, Pulse 107, Oxygen Saturation 100 %, Respiration 19, Temperature 95. F. There was no documentation noted in the record for physician notification of the temperature level. At 1:45 PM - Blood Pressure 152/52, Pulse 103, Oxygen Saturation 100 %, Respiration 17, Temperature 97.9 F. At 1:54 PM - Blood Pressure 145/53, Pulse 107, Oxygen Saturation 100 %, Respiration 16, Temperature 98.2 F. At 2:00 PM - Blood Pressure 113/46, Pulse 105, Oxygen Saturation 100 %, Respiration 55. There was no notification of physician or blood bank notification documented in the record of the respiratory rate increase. Temperature 98.4 F. At 2:15 PM - Blood Pressure 129/49, Pulse 112, Oxygen Saturation 100 %, Respiration 26, Temperature 95.0 F. There was no notification of the physician or blood bank documented in the record of decreased temperature level. At 2:30 PM - Blood Pressure 126/50, Pulse 118, Oxygen Saturation 100 %, Respiration 31, Temperature 98.4 F. At 3:00 PM - Blood Pressure 168/60. There was	A 385		

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no physician notification of the blood pressure elevation noted in the record. Pulse 106, Oxygen Saturation 100 %, Respiration 18, no temperature was documented.

At 3:15 PM- Blood Pressure 159/51, No additional vital signs were noted.

At 3:30 PM- Blood Pressure 152/49, No additional vital signs were noted.

At 3:45 PM -Blood Pressure 154/48, No additional vital signs were noted.

At 4:00 PM - Blood Pressure 149/47, Pulse 94, Oxygen Saturation 100 %, Respiration 16, no temperature was documented.

At 4:30 PM - Blood Pressure 152/59 - No additional vital signs were noted.

The next entry for vital signs was at 8:00 PM, Temperature was 98.1. There was no documentation in the record at this time for blood pressure, heart rate, respiration, or Oxygen saturation.

Patient #57:

History and Physical dated [redacted], dictated by the Hospitalist MD #5 revealed the following:

Patient #57 was a 55-year-old female with a history of atrial fibrillation, liver cirrhosis secondary to hepatitis C virus, end stage renal disease secondary to failed allograft on Hemodialysis (HD) right brachial graft. Pt# 57's

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active problems were listed as End Stage Renal disease (HCC) and Cirrhosis (HCC)."

A progress note from Hospitalist MD #7 on [redacted] revealed the following:

"Patient #57 was transferred to Surgical ICU on [redacted] with hemorrhagic shock. Hemoglobin was 6 and 2 units of PRBC's (Packed Red Blood Cells) were infused. Patient #57 was taken back to the Operating room for an exploratory laparotomy. The exploratory laparotomy revealed 1500 ml of clot posterior to the liver with a serosanguineous ascites within the abdomen. Arterial bleeding at the gallbladder fossa was identified and over sewn."

Review of the blood transfusion record for Patient #57 on [redacted], revealed the following:

An order for type and screen, and transfuse one unit was entered on [redacted], at 12:33 PM.

The blood transfusion record did not indicate a start time for the blood transfusion or a time when the blood product was picked up from the laboratory. There was a note on [redacted], at 5:00 PM., that noted rate change but the note did not indicate what the rate had been changed to. There was a note that indicated a new bag was hung on [redacted], at 5 :15 PM. The stop time was noted to be 7:44 PM.

The nurse listed on the transfusion record was RN #27. The second signature/RN verification was RN #28.

Vital Signs were listed as below:

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At 5:15 PM- Blood Pressure 118/53, Heart rate 82, Oxygen Saturation 98%, Respiration 23, Temperature 97.8 F.

At 5:45 PM - No Blood Pressure was documented, Pulse 80, Oxygen Saturation 90%, Respiration 25. There was no documentation noted in the record for physician/blood bank notification of the oxygen saturation level decreasing 8%. There was no documentation in the nursing notes for the decreased oxygen level.

At 6:00 PM - There was no Blood Pressure documented. Pulse 77, Oxygen Saturation 100 %, Respiration 18, Temperature 97.8 F.

At 6:30 PM - There was no Blood Pressure documented. Pulse 80, Oxygen Saturation 92%, Respiration 16. There was no documentation in the blood transfusion record or nurses note that addressed the oxygen saturation declining 5 %.

At 7:00 PM- There was no Blood Pressure documented. Pulse 76, Oxygen Saturation 100%, Respiration 11. There was no temperature documented. There was no documentation of physician notification in the nurse's notes regarding the respiration rate decreasing to 11.

At 7:43 PM - Blood Pressure 122/64, Pulse 79, Oxygen Saturation 100 %, Respiration 23, Temperature 97.8 F.

At 8:09 PM Blood Pressure 133/61, Pulse 78. Oxygen Saturation 97%, no Respiration rate or Temperature was documented.

At 9:11 PM was the next time vital signs were

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documented. Blood Pressure 115/67, Pulse 78, Respiration 17, no oxygen saturation or temperature was documented.

At 10:09 PM - Blood Pressure 112/65, Pulse 80, Respiration 22, Oxygen Saturation 100 %, no temperature was documented.

Patient #47:

Review of the Internal Medicine History & Physical revealed, Patient #47 was a 75-year-old male with past medical history of Prostate Cancer, status post radiation who presented to the emergency department with hematuria and had worsened over the last few evenings. Patient #47 had low systolic blood pressure in the emergency department and was given blood transfusion and IV fluids.

Review of the emergency department record revealed Patient #47 arrived in the emergency department at 5:54 PM on [redacted]. Triage was documented at 5:57 PM.

Review of the patient timeline revealed the following:

[redacted]

At 2:23 AM - Type & Screen was ordered by Emergency Department (ED) MD #8.

At 6:59 AM - ED MD # 8 notes low Blood pressure. Clinical appearance- will give blood products

At 3:30 AM - Blood labels were printed

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A 385	Continued From page 39 At 3:42 AM - Type & Screen collected At 4:33 AM - Type & Screen resulted At 4:54 AM - Order for repeat H&H (Hemoglobin & Hematocrit) was ordered by ED MD #8 At 5:43 AM - Order for repeat Type & Screen was entered. At 6:57 AM - Order for Transfuse 2 Units RBC by ED MD #8 Review of the Blood Transfusion Record revealed the following: First Unit of PRBC (Packed Red Blood cells) The nurse listed on the transfusion was RN #20. The verification/2nd RN was listed as RN #21. The start time for the first unit of blood was listed as 9:29 AM, [redacted], and the stop time was listed as 11:50 AM, [redacted], on the transfusion record. The time indicating when the blood product was picked up from the lab was not documented in the record. Vital Signs were noted on the blood transfusion as follows: At 9:25 AM - Blood Pressure 84/53, Pulse 99, Oxygen Saturation 100 %, Respiration 22, Temperature 98.6 F. At 9:44 AM - Blood Pressure 83/69, Pulse 98,	A 385		

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A 385	Continued From page 40 Oxygen Saturation was 95%. There was no notation in the record for the change of 5% in the Oxygen Saturation. Respiration 21. Temperature 98.6 F. At 10:15 AM - Blood Pressure 87/56, Pulse 94, Oxygen Saturation 99%, Respiration 20, Temperature 98.3 F. There was a note in the patient medical record that said, RN#20 notified the attending MD regarding patient status. At 10:29 AM - Blood Pressure 95/52, Pulse 93, Oxygen Saturation 98%, Respiration 21, Temperature 98.2 F. At 11:40 AM - Blood Pressure 87/56, Pulse 95, Oxygen Saturation 83%. There was a note from RN #20 that said, "the pulse oximeter was removed." There was no follow up with the Oxygen Saturation been documented. Pulse 95, Respiration 22, Temperature 98.3 F. At 12:00 PM - Blood Pressure 102/56, Pulse 95, Oxygen Saturation 100%, Respiration 21, Temperature 98.2 degrees F. At 1:54 PM was the next vital signs documented in the medical record. Blood Pressure 103/59, Pulse 100, Oxygen Saturation 99, Respiration 22, and Temperature 98.8 F. On [redacted] at 11:30AM, RN #20 was asked what the hospital used to identify possible blood transfusion reactions. RN #20 said, the computer notifies you anytime there is an abnormal vital sign, but I am always with my patients at the bedside, so I would recognize them.	A 385		

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A 385	Continued From page 41 During an interview on January 8, 2019, at 9:54 AM, the Environmental Services (EVS) Director was asked what the responsibilities were for the EVS technicians in the Emergency Department. EVS Director said the EVS staff clean counter tops, cabinets, stretchers, high dust the rooms, and sanitize all surfaces. EVS director was asked what the responsibilities were for EVS staff when they found specimens of blood, bodily fluids in the room. EVS director said they are to stop and notify the nurse. EVS staff will not clean the room until the nurse removes the blood/urine specimens. EVS said all staff had been trained on the "New" protocol about a month ago. EVS director was asked to provide documentation of the training conducted with EVS staff. The EVS Director provided a document dated June 18, 2018, which was prior to the incident that occurred in [redacted], involving Patient #27. No documentation was provided on staff training/education for cleaning patient rooms in the emergency department. During an interview on January 8, 2019, at 10:16 AM: Patient Care Assistance (PCA) #1 was asked if her job duties included drawing lab specimens. PCA #1 confirmed it did. PCA #1 was asked if she had received training on drawing lab specimens. PCA #1 confirmed she had, but did not draw lab much anymore. PCA #1 said the Emergency Department now had a full time phlebotomist and they drew most of the laboratory test. PCA #1 was asked what training she had received on	A 385		

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blood transfusions/specimen labeling in the last month. PCA #1 said she could not recall any training she had received on those subjects.

During an interview on January 8, 2019, at 11:30 PM:

RN #20 was asked what method/system the hospital used to identify possible blood transfusion reactions. RN #20 said, the computer notifies you anytime there is an abnormal vital sign, but I am always with my patients at the bedside, so I would recognize them. RN #20 said, the system also recognizes signs of sepsis and would alert you for those as well. RN #20 was asked what training on blood transfusion reactions she had received in the last month. RN #20 said, we do yearly training every year but could not remember any additional training.

During an interview on January 8, 2019, at 4:00 PM:

RN #32 was asked what vital signs were required per hospital policy on blood transfusions and where the vital signs should be documented in the record. RN #32 said, she wasn't exactly sure what the hospital policy said without looking at it but she documented every 15 minutes in the blood transfusion record. RN #32 was asked what method/system the hospital used to identify possible blood transfusion reactions. RN #32 said, the computer would alert you of the abnormal vital signs. RN #32 was asked what the policy said on possible blood transfusion reactions. RN #32 said, you would stop blood, call blood bank, call physician, fill out blood

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A 385	Continued From page 43 transfusion reaction form, and send blood back to lab. RN #32 was asked what training she had received on blood transfusions/ specimen labeling in the last month. RN #32 said, the staff is required to complete yearly training on blood transfusions. RN #32 was not aware of any additional training she has received on blood transfusion. RN #32 was asked if she had received any training on changes for drawing lab/labeling lab specimens in the last month. RN #32 said, she had only been there a few months so no changes had been made that she knew of since her start date. RN #32 said, she was taught to only draw the lab for the ordered test. No extra tubes were drawn. RN #32 said, the specimen tubes were required to be labeled with a lab label, not a patient label. RN #32 said the lab label printers were in the rooms. Patient #51: Review of the ED notes on Patient #51 revealed, she was a 73-year-old female who presented on [redacted], at 12:11 PM. Patient #51 presented for fluid overload after dialysis. Review of the ED record revealed a physician's order was written at 6:52 PM., to "Prepare RBC and platelets." There was documentation on the record that the order was discontinued at 7:01 PM. There was no order on the record for Patient #51 to be Typed and Screen for a transfusion. Review of the hospital ED occurrences dated [redacted], revealed the Transfusion Service received a request for 1 unit of Red Blood Cell and 1 unit of Platelets on the wrong patient. The blood product orders were received without a	A 385		

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Type and Screen. The ED was called to add test and informed the order was placed on the wrong patient. The incorrect order was canceled and the correct order was placed. There was no documentation on the form as to what corrective action was implemented. Patient #'s 51 and 52 were the patients involved in the incident.

During an interview on January 9, 2019, after 9:54 a.m., RN #33 (ED Director) and RN #51 confirmed the missing information in the patient's electronic medical record. RN #51 confirmed the order was written in error on Patient #51's chart.

Patient #52:

Review of the Emergency Department (ED) notes on Patient #52 revealed, she was a 66-year-old female who presented to the ED at 2:16 PM. Patient #52 presented to the ED 2 hours after Patient #51 arrived. Patient #52 presented with abnormal laboratory values and melena (dark stools).

Review of laboratory results dated [redacted], at 2:31 PM. revealed the following low results:

Hemoglobin 7.7 (reference ranges 11.2-15.7)

Hematocrit 24.2 (reference ranges 31.1-44.9)

Platelet 39 (reference ranges 150-450)

Review of a physician's history and physical dated [redacted], revealed Patient #52 had diagnoses which included acute blood loss

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A 385	Continued From page 45 anemia and pancytopenia (low platelet level). The plan was to transfuse one unit of packed Red Blood Cells and one unit of Platelets. At 3:58 PM, a physician's order was written to Prepare and Transfuse Leuko- Red RBC, 1 unit, and to Prepare and Transfuse Leuko- Red PLT (platelet), 1 unit. At 3:59 PM., a physician's order was written to cancel the transfusion orders. At 7:03 PM., (3 hours later) physician's order were rewritten to prepare and transfuse the platelets and red blood cells. According to the Transfusion records and vital sign sheets the following was documented: [redacted]: Unit #1 Platelets started at 7:38 PM. and stopped at 8:16 PM. The Platelets infused in over 38 minutes. The physician's order did not indicate how quickly to infuse the Platelets. Review of documentation revealed vital signs were taken at 7:37 PM., 7:52 PM., and 8:16 PM. and 8:44 PM. The first unit of RBCs (Red Blood Cells) were started at 8:44 PM. There was no documentation of a post vital signs documented after the completion of the platelets at 8:16 PM. and start of the Red Blood Cells at 8:44 PM. Review of a Transfusion record dated [redacted]	A 385		

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[redacted], revealed Patient #52 received another unit of packed Red Blood Cells. The unit of blood was started at 1:49 PM., stopped at 6:00 PM. and completed at 6:40 PM. (over 4.5 hours).

During an interview on January 9, 2019, after 9:54 AM., RN#33 (ED Director) and RN #51 confirmed the missing information in the chart, start times of the blood and physician orders.

During an interview on January 9, 2019, after 2:55 PM., The Quality Director provided the incident information record dated [redacted], which revealed the incident was a near miss (an unplanned event that did not result in injury, illness or damage but had the potential to do so). There was no documentation as to what intervention was implemented to prevent this type of incident from occurring again.

The Quality Director was asked what was implemented and he reported that the error was caught by the laboratory and that it was just human error. The nurse put the order in the wrong patient record. He was shown the physician had put the order in. He reported the physician was notified of the order and the incident was not escalated to the Medical staff.

Patient #59:

Review of the ED notes on Patient #59 revealed, he was a 62-year-old male who presented to the ED on [redacted], at 6:37 PM. Patient #59 had complaints of general weakness and a headache.

Review of a physician's history and physical

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dated [redacted], revealed, Patient #59 had diagnoses which included colon cancer with metastasis, rectal bleeding and a hemoglobin of 4 (reference ranges being 13.7-17.5). Patient #59 was also diagnosed as being septic /hypovolemic shock.

At 8:52 PM., Patient #59 received orders to type and screen, prepare and transfuse RBC (Red Blood Cells), 3 units. According to transfusion records Unit #1 was started on [redacted], at 10:51 PM.

Review of ED notes revealed the following:

At 11:08 PM, nursing documented that Patient #59 started losing consciousness.

At 11:09 PM, the blood was stopped.

At 11: 10 PM, CPR was initiated.

At 11:19 PM, Patient #59 was intubated.

At 11:29 PM, transfusion reaction investigation.

At 11:30 PM, blood bank notified of transfusion reaction ...

Review of the medication administration record dated [redacted], revealed, Patient #59 received the medications magnesium sulfate and protonix during the time the blood transfusion was infusing. Nursing failed to document in the chart which intravenous access was used to give the medications, which could be potentially incompatible with the blood.

Review of documentation on the transfusion

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A 385	Continued From page 48 record revealed unit #1 was stopped on "[redacted]" at 8:00 AM. (4 days later). Review of the ED record revealed Patient #59 was transferred to Intensive Care Unit (ICU) on [redacted]. Review of the transfusion records revealed Patient #59 received two more units of blood. Unit #2 was started on [redacted], at 12:41 midnight and stopped at 1:13 AM. Unit #3 was started on [redacted], at 12:48 midnight and stopped at 1:13 AM. The completion time documented on both forms was at 12:43 midnight before the stop times. During an interview on January 9, 2019, after 1:00 PM., RN #40 and RN #39 revealed that the computerized system would not allow you to put the correct stop time in the system for the transfusions. The times in Patient #59's chart were errors. RN#39 confirmed that nursing did not document the intravenous access they used to administer the medication. RN #39 identified the area on the medication administration record that nursing should use to document intravenous access used. During an interview on January 9, 2019, after 2:55 PM., the Quality Director revealed not knowing about the potential transfusion reaction on Patient #59 which occurred on [redacted]. The Quality Director reported he knew for sure he did not have the one on Patient #59 and that they do not send all blood transfusion reactions through the quality program.	A 385		

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Patient #61:

Review of the ED notes on Patient #61 revealed, he was a 59-year-old male who presented to the ED on [redacted], at 1:21 PM.

Review of ED notes timed for 1:33 PM., revealed, Patient #61 reported having fatigue and had a history of lung cancer.

At 1:33 PM., an order was written for a Type and Screen.

At 2:52 PM., orders were placed for "CBC with Platelet count +automated diff; Type and screen, automated; Prepare Leuko-Red RBC; sodium chloride 0.9%(NS) infusion; Transfuse Leuko-Red RBC, 2 units."

Review of the laboratory results timed 3:55 PM., revealed the following low results:

Red blood cell count 2.43 (reference ranges 4.63-6.08)

Hemoglobin 5.3 (reference ranges 13.7-17.5)

Hematocrit 17.6 (reference ranges 40.1-51.0)

According to the Transfusion records and vital sign sheets the following was documented: Unit #1 was started at 4:14 PM. and down at 6:08 PM. (less than 2 hours).

Review of vital signs revealed the following:

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At 4:08 PM., complete vitals were documented as 98.0 degrees Fahrenheit, Pulse 110, Respiratory rate 18, Oxygen saturation 96 percent, and Blood Pressure of 132/77.

At 4:35 PM., the Oxygen Saturation and Blood Pressure were not documented.

At 6:01 PM., over 1.5 hours later vital signs were documented. The Pulse and Oxygen Saturation were not documented.

At 6:05 p.m., the Temperature, Respiratory rate and Blood Pressure were not documented.

Review of the transfusion record revealed Unit #2 was started at 6:05 PM. Review of vital signs revealed the following:

At 6:05 PM. there was no documentation of a Temperature, Respiratory rate, and Blood Pressure.

At 6:27 PM., the temperature was 96.3 Fahrenheit degrees;

At 7:30 PM. the Temperature was 97.3 Fahrenheit degrees;

At 8:35 PM., the Temperature was 98.5 Fahrenheit degrees.

There was no alert in the system with the 2 degrees' increase of the temperature nor physician notification of the increase in temperature after the start of second unit of blood.

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A 385	Continued From page 51 Review of the transfusion record revealed Unit #2 was stopped at 8:35 PM. The next documentation of post vital signs was at 11:00 PM. (over 2.5 hours later). During an interview on January 9, 2019, after 1:00 PM., RN #40 (Quality) and RN #39 confirmed the missing vital signs. During an interview on January 8, 2019, after 9:12 AM., RN#33 (ED Director) reported the incident occurred [redacted] or [redacted] and occurred because of a mislabeled blood tube. RN #33 (ED Director) reported that as today all of her staff had not been trained yet. They were providing the information during daily huddles, but they did not have written agendas. RN #33 stated "Someone from quality was going around now (January 8, 2019) to staff and performing verifications and having them sign that they know the new procedures." The environmental services staff are not supposed to clean the rooms if blood tubes are left in the room. They were still working on the plan as to how it would work. During an interview on January 8, 2019, after 10:33 AM., RN #36 reported that she learned about the new process of getting a second blood sample after obtaining a type and screen on January 1, 2019. RN #36 reported that she had not received the training on blood transfusion and adverse reaction. She was surprised by blood bank when they called asking for another sample on one of her patients on January 1, 2019. RN #36 reported she assumed it must be because of the incident that occurred in [redacted] were the patient died after the wrong blood	A 385		

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transfusion was administered.

During an interview on January 8, 2019, after 10:51 AM., the Quality Director reported that as a result of their investigation on the incident they found the following problems:

1. A failure to follow their process for labeling in the ED.

2. A failure to recognize changes of blood transfusions reactions in the Intensive care unit.

The Quality Director reported the information about the new processes went to staff on December 21, 2018, and were effective January 1, 2019.

During an interview on January 8, 2019, after 11:26 AM., Phlebotomist #1 reported that she had not been talked to about labeling blood samples.

During an observation on January 8, 2019, after 11:39 AM., Phlebotomist #1 printed lab labels off for Patient #50 at the nurse's station. Three labels were taken into Patient #50's room. After collecting the blood specimens, Phlebotomist #1 placed the labels on the specimen tubes.

During an interview on January 8, 2019, after 2:08 PM., RN #37 and the Transfusion Service quality staff member reported not knowing that phlebotomist were drawing blood in the ED. RN #37 reported the phlebotomist were not supposed to print labels outside the patient's room because it increased the chances for errors.

Patient #16:

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A 385	Continued From page 53 Patient #16 was observed on [redacted], at 8:50 AM, in the Intensive Care Unit of the facility at 7 South 2. The patient was alert and oriented to person, place, time, and situation. The patient had a right arterial line and central venous catheter in place for hemodialysis treatment. Interview on [redacted], at 8:50 AM., with Registered Nurse (#11) revealed, Patient#16 had plasma transfusions on [redacted], and was scheduled for hemodialysis today ([redacted]). Interview with Patient#16 on [redacted], at 8:52 AM, revealed he has been in the hospital since [redacted], and have had numerous blood transfusions. Review on January 8, 2019, of Patient#16's clinical record revealed a physician's history and physical dated [redacted], which indicated the patient was admitted to the facility on [redacted] with diagnoses of gastrointestinal bleed, anemia, cirrhosis, and encephalopathy. Physician's impression: "Acute blood loss anemia, acute encephalopathy, decompensated cirrhosis. " Review of the patient's clinical record revealed a blood and blood product consent, signed on [redacted], and a physician's order dated [redacted], at 1:53 AM., to transfuse leuko red blood cells two units. Review of the patient's clinical record revealed a single blood transfusion record with documentation which indicated the patient was transfused one unit leuko red blood cells, unit	A 385		

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A 385	Continued From page 54 # [redacted] on [redacted]. The single blood transfusion record revealed, the blood transfusion began on [redacted], at 3:17 AM., and the transfusion was stopped and completed on [redacted], at 6:04 AM. The record indicated complete and partial sets of vital signs were taken on [redacted], which included the following: At 3:15 AM.: Patient's Temperature; 98.6 degrees F, Pulse 118 beats per minute, Respiration 25, Oxygen Saturation (SpO2) 100%, Blood Pressure 122/71, and shock index of 0.66. At 3:30 AM.: Patient's Temperature; 99.2 degrees F, Pulse 119 beats per minute, Respiration 22, Sp02 100%, Blood Pressure 100/50, and shock index 1.18. At 3:33 AM.: Patient's Pulse 117 beats per minute, Respiration 22, Sp02 100%, arterial pressure 103/49, MAP 69mmHG and shock index 0.6. At 4:00 AM.: Patient's Pulse 120 beats per minute, Respiration 24, and Sp02 100%. At 4:02 AM.: Patient's Blood Pressure 104/54. At 4:30 AM: Patient's Pulse 117 beats per minute, Respiration 22, and Sp02 100%. At 4:32: Patient's Blood Pressure 96/51 and MAP 67mmHG. At 5:00 AM.: Patient's Pulse 114 beats per	A 385		

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minute, Respiration 30, Sp02 100%, Blood Pressure 102/67 and MAP 79 mmHG and 0.61.

At 5:02 AM.: Patient's Blood Pressure 97/50.

At 5:30 AM : Patient's Pulse 117 beats per minute, Respiration 20, and Sp02 100%.

At 5:47 AM.: Patient's Sp02 100%.

At 6:00 AM.: Patient's Temperature; 99.2 degrees F, Pulse 122 beats per minute, Respiration 29, Sp02 100%, Blood Pressure 123/62, and shock index 0.99.

Review of the patient's single blood transfusion record revealed, during the blood transfusion the patient's temperature was monitored at 3:30 AM. and 6:00 AM. There was no hourly temperature documented after initiation of the transfusion.

Further review of Patient #16's clinical record revealed documentation on the patient's single transfusion record which indicated a second unit leuko red blood cell, 350 mls, unit # [redacted] was administered to the patient on [redacted]. The record indicated the transfusion began on [redacted], at 11:57 AM, and the transfusion was stopped at 12:20 PM.

The record indicated the following full and partial sets of vital signs were monitored during the transfusion:

At 11:45 AM.: Patient's oral Temperature; 98.6 degrees F, Pulse 92 beats per minute, Respiration 16, SpO2 100%, Blood Pressure 94/55, MAP mmHg 65, and shock index of 0.98.

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A 385	Continued From page 56 At 11:57 AM.: Patient's oral Temperature; 98.6 degrees F, Pulse 105 beats per minute, Respiration 18, SpO2 100%, Blood Pressure 94/55, and shock index of 1.12. At 12:00 PM.: Patient's Pulse 98, Respiration 27, Sp02 100%, Blood Pressure 87/53, MAP 62 (mmHg), and shock index 1.13. At 12:15 PM.: Patient's Pulse 99, Respiration 23, Sp02 100%, Blood Pressure 91/58, MAP 69 (mmHg), and shock index 1.09. There was no Temperature documented fifteen minutes after initiation of the transfusion. The record revealed at the time the transfusion was stopped at 12:20 PM., partial vital signs of Temperature of 98.6 and Spo2 of 100% were recorded. Review of Patient #16's clinical record revealed a blood and blood product consent signed on [redacted], and a physician's order dated [redacted], to transfuse two-unit fresh frozen plasma. Review of the Patient's clinical record revealed a single transfusion record with documentation which indicated, the patient was transfused fresh frozen plasma 214 mls, unit #[redacted] on [redacted]. The record indicated that the transfusion began on [redacted], at 2:35 PM, stopped at 3:15 PM, and completed on [redacted], at 3:26 PM. The record indicated the following sets of vital	A 385		

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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 385	Continued From page 57 signs were done during the blood transfusion on [redacted]: At 2:30 PM: Patient's axillary Temperature; 97 degrees F, Pulse 92 beats per minute, Respiration 20, SpO2 98%, Blood Pressure 105/44, MAP (mmHg) 58, and shock index of 0.88. At 2:45 PM: Patient's axillary Temperature of 97.3 degrees F, Blood Pressure of 105/38, and a MAP of 53. At 3:00 PM: Patient's axillary Temperature; 96.8 degrees F, Pulse 93 beats per minute, Respiration 24, SpO2 97%, Blood Pressure 120/40, MAP (mmHg) 57, and shock index of 0.85. At 3:15 PM: Patient's axillary Temperature; 96.8 degrees F, Pulse 90 beats per minute, Respiration 29, SpO2 98%, Blood Pressure 119/40, MAP (mmHg) 58, and shock index of 0.76. There was no documentation in the patient's clinical record that the patient's Pulse, Respiration, SpO2 and shock index were monitored 15 minutes after initiation of the transfusion at 2:35 PM. Patient #17: Patient #17 was observed on the 6th floor intensive care unit on [redacted], at 10:30 a.m. The patient was alert but responded only with eye movement. He had a tracheostomy in place to ventilator. The patient's wife and	A 385		

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A 385	Continued From page 58 daughter were present at the patient's bedside during the observation. Interview with the patient's daughter at that time revealed, Patient #17 had multiple transfusions since his admission to the hospital. Interview on January 8, 2019, at 10:40 AM, with RN #14 who was assigned to the patient revealed, the patient had a liver transplantation and had a tracheostomy inserted on [redacted]. She said the patient had slow dialysis treatment the previous night, and had received blood transfusions but she could not recall the date or time of the transfusions. Review on January 10, 2019, of patient #17's clinical record (physician's history and physical), located in the electronic medical record, revealed the patient was admitted to the facility on [redacted], with diagnosis of acute kidney injury. Review of the Patient's electronic medical record and hard chart located on the unit, revealed a physician's order dated [redacted], to transfuse one unit of red blood cells. Review of the patient's clinical record revealed a single transfusion record dated [redacted], unit number [redacted]. The record indicted that the red blood cells was transfused on Patient #17 on [redacted]. The transfusion record did not indicate the volume of red blood cells administered to the patient. The single transfusion record indicated, the blood transfusion began on [redacted], at 2:43	A 385		

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A 385	Continued From page 59 PM. and the transfusion was completed on [redacted], at 11:50 AM. The record indicated complete and partial sets of vital signs were taken on [redacted], which included the following: At 2:43 PM: Patient's Temperature; 97.8 degrees F, Pulse 81 beats per minute, Respiration 12, SpO2 100%, Blood Pressure 122/71, and shock index of 0.66. At 3:00 PM: Patient's Pulse 81, Respiration 20, Sp02 100%, and shock index 0.74. At 3:25 PM: Patient's Temperature 96.4, Pulse 81, Respiration 11, Sp02 100%, Blood Pressure 115/64, and shock index 0.7. At 4:00 PM: Patient's Temperature 97.2, Blood Pressure 116/64, pulse 79, Respiration 19, Sp02 100%, and shock index 0.68. At 5:00 PM: Patient's Pulse 82, Blood Pressure 123/68, Respiration 11, Sp02 100%, and shock index 0.67. There was no documentation of a Temperature taken on the patient. At 6:00 PM: Patient's Pulse 83, Respiration 23, Sp02 100%, and shock index 0.69. There was no documentation of a Temperature taken on the patient. At 7:00 PM: Temperature 97.7, Pulse 86, Respiration 18, Sp02 100%. Review of the single transfusion record revealed documentation which indicated, the unit of red blood cells was completed on [redacted], at	A 385		

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A 385	Continued From page 60 11:50 AM., approximately 4 days after it was initiated. There was no indication that a Temperature or Blood Pressure was taken on the patient 15 minutes' post initiation of the transfusion. There was no indication/ documentation in the clinical record of the licensed staff who witnessed completion of the red blood cells. The record indicted monitoring of the patient until [redacted], at 11:50 AM. Interview on January 9, 2019, at 11:35 AM with the Unit's Nurse Manager (RN #13) revealed, she did not know why the blood transfusion was initiated on [redacted] and completed on [redacted]. RN #13 stated that she received a safety alert on [redacted], regarding blood transfusion and monitoring of patients' vital signs. She said she had a huddle on the unit with staff on Monday January 7, 2019, and Tuesday and January 8, 2019, (during the survey) to discuss the safety alert but did not do a formal in-service. RN #13 indicated that prior to the safety alert, she was not aware that there was an issue with administration of blood and blood product. She said she is provided with a daily report from the information technology nurse on patients who receive transfusion on the unit, but she did not review every transfusion record. Interview on January 10, 2019, at 1:49 PM., with Registered Nurse (RN #12) whose name appeared on the single blood transfusion record revealed, she had hung the unit of red blood cells on Patient #17. The Surveyor reviewed the patient's single blood transfusion record with RN #12. She said the missing vital signs were	A 385		

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A 385	Continued From page 61 "inadequate documentation" by her. Patient # 18: Review of Patient #18's clinical record (demographic data) revealed, he was admitted to the facility on [redacted], with diagnoses of gastrointestinal bleed, hypotension and septic shock. Review of the Patient's clinical record revealed a physician's order located in the electronic medical record dated [redacted], to transfuse one unit red blood cells. Review of the patient's clinical record, revealed a single transfusion record dated [redacted], with blood unit number W0562 18 010829 P -E0424V00. The record indicted that the red blood cells was transfused to Patient #18 on [redacted]. The transfusion record indicated the total volume of red blood cells administered to Patient #18 was 400 milliliters. The record indicated that the blood transfusion began on [redacted], at 1:44 AM and the transfusion was stopped and completed on [redacted], at 5:33 AM. The record indicated complete and partial sets of vital signs were taken on [redacted], which included the following: At 1:44 AM: Patient's Temperature; 97.7 degrees F, Pulse 98 beats per minute, Respiration 22, Sp02 95%, Blood Pressure 83/59, and shock	A 385		

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A 385	Continued From page 62 index 1.18. At 1:45 AM: Patient's Pulse 98 beats per minute, Respiration 23, Sp02 79%, Blood Pressure 83/59 MAP 65, and shock index 1.18. At 2:00 AM: Patient's Temperature; 97.8 degrees F, Pulse 98 beats per minute, Respiration 24, Sp02 96%, Blood Pressure 97/72, MAP 80, and shock index 1.01. At 2:15 AM: Patient's Pulse 95 beats per minute, Respiration 13, Sp02 100%. At 2:30 AM: Patient's Pulse 98 beats per minute, Respiration 22, Sp02 97%. At 2:45 AM: Patient's Pulse 100 beats per minute, Respiration 16, Sp02 93%. At 4:30 AM: Patient's Temperature; 97.6 degrees F. At 5:00 AM.: Patient's Temperature; 97.5 degrees F, Pulse 91 beats per minute, Respiration 23, Sp02 100%, Blood Pressure 123/90, MAP 80, and shock index 0.74. At 5:15 AM: Patient's Pulse 87 beats per minute, Respiration 15, and Sp02 100%. At 5:30 AM: Patient's Pulse 91 beats per minute, Respiration 14 and Sp02 100%. The Patient's complete vital signs including his Temperature and Blood Pressure were not monitored every hour during the transfusion as dictated by the hospital current policy on	A 385		

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A 385	Continued From page 63 Transfusion of Blood Products Patient Care; Document identification: 2_Reg_ Transfusion Blood _ Products _PP "Monitor vital signs and assess temperature and urine throughout the transfusion process to monitor for adverse reactions to blood products and the effectiveness of treatment. Vital signs are done every hour, and when the transfusion is complete." Patient #19: Patient #19 was observed on 8A intensive care unit on [redacted], at 2:25 PM. The patient was alert and oriented X1 to name. Interview on January 9, 2019, at 2:25 PM, with Registered Nurse (RN #42) revealed, the patient was admitted to the facility due to a fall with a fracture of the right hip and status post ORIF (open reduction internal fixation). The Patient had a left intra jugular triple lumen catheter inserted on [redacted]. Review on January 9, 2019, of the patient's clinical record (demographic data) revealed the patient was admitted on [redacted], with diagnoses of closed transverse fracture of anterior and posterior Acetabulum with ORIF on [redacted]. Review of the Patient's clinical record revealed a physician's order in the electronic medical record, dated [redacted], to transfuse one unit red blood cells. Review of the patient's clinical record revealed a single transfusion record dated [redacted], with blood unit number W0446 18 389506 Y -	A 385		

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A 385	Continued From page 64 E0336V00. The record indicted that the red blood cells was transfused to Patient #19 on [redacted]. The blood transfusion record indicated, the total volume of red blood cells administered to Patient #19 was 600 milliliters. The single blood transfusion record indicated, the transfusion began on [redacted], at 5:18 AM, and the blood transfusion was stopped on [redacted], 2:30 PM and completed on [redacted], at 10:39 AM. The record indicated complete and partial sets of vital signs were taken on [redacted], which included the following: At 5:00 AM: Patient's Pulse 72 beats per minute, Respiration 17, Sp02 100%, arterial pressure 143/56, MAP 82, and shock index 0.5. At 5:18 AM: Patient's Temperature; 98.1 degrees F, Pulse 74 beats per minute, Respiration 17, Sp02 100%, Blood Pressure 138/54, and shock index 0.54. At 6:00 AM: Patient's Pulse 70 beats per minute, Respiration 19, Sp02 100%, and arterial pressure 140/54 MAP 80. At 7:00 AM: Patient's Pulse 76 beats per minute, Respiration 19, Sp02 100%, arterial pressure 126/47, MAP 69, and shock index 0.6. At 7:15 AM: Patient's Pulse 80 beats per minute, Respiration 23, Sp02 99%, Blood Pressure 97/53, MAP 82, and shock index 0.57.	A 385		

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A 385	Continued From page 65 At 7:30 AM: Patient's Pulse 79 beats per minute, Respiration 22, Sp02 100%, arterial pressure 128/52, MAP 74, and shock index 0.62. At 8:00 AM: Patient's Temperature; 98.1 degrees F, Pulse 78 beats per minute, Respiration 26, Sp02 100%, and shock index 0.62. At 8:15 AM: Patient's Pulse 79 beats per minute, Respiration 21, Sp02 100%, and Blood Pressure 102/67 MAP 79, and shock index 0.61. At 8:30 AM: Patient's Pulse 79 beats per minute, Respiration 24, Sp02 100%, and arterial pressure 126/48 MAP 69, and shock index 0.63. At 8:45 AM: Patient's Pulse 81 beats per minute, Respiration 34, Sp02 99%, and arterial pressure 136/51, MAP 75, and shock index 0.6. At 9:00 AM: Patient's Pulse 82 beats per minute, Respiration 26, Sp02 100%, and arterial pressure 122/42, MAP 64, and shock index 0.67. At 9:15 AM: Patient's Pulse 82 beats per minute, Respiration 20, Sp02 100%, and arterial pressure 121/47, MAP 68, and shock index 0.68. Review of the patient's blood monitoring record revealed during the blood transfusion the patient's temperature was monitored at 5:18 AM and 8:00 AM revealed that there was no 15-minute Temperature documented after initiation of the transfusion. The record indicated that the patient's blood transfusion began on [redacted], at 5:18 AM and the transfusion was stopped on [redacted] at 2:30 AM, and completed on [redacted]	A 385		

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A 385	Continued From page 66 [redacted], at 10:39 AM. The completion time documented in the patient's clinical record indicated that the transfusion time was approximately 53 hours. The facility's current policy directs staff as follows: Transfusion of Blood Products Patient Care; Document identification: 2_Reg_ Transfusion Blood _ Products _PP "Infusion time should not exceed 4 hours. Monitor vital signs and assess temperature and urine throughout the transfusion process to monitor for adverse reactions to blood products and the effectiveness of treatment. Vital signs are done every hour, and when the transfusion is complete." Interview on January 9, 2019, at 3:35 PM with the hospital Patient Care Nursing Administrator (RN #41) revealed, the two Registered Nurses responsible for dual sign off on the blood transfusion record were traveling nurses (RN #16 and RN # 17) who were on a 26 week nursing rotation at the hospital. She said the traveling nurses' competency are done by the contracting agency and a three days' orientation completed in the facility before assuming patient care duties. Review on [redacted], of Registered Nurse (#17's) (traveling nurse) personnel and training file, reviewed with (the Director of Training and Education) revealed no evidence of a critical care contract nurse orientation syllabus. Interview with the hospital Director of Training and Education during the personnel training file review revealed, the hospital has been looking for the critical care contract nurse orientation syllabus for Registered Nurse (#17) but could not locate it. She said this is a requirement completed	A 385		

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A 385	Continued From page 67 by traveling nurses working in the critical care area of the facility. Interview on January 7, 2019, at 3:13 PM with the Kidney Liver Transplant Unit Director (RN #35) revealed, she generally provides training to staff during staff meeting. She said the updated training on blood transfusion came out [redacted], but her staff had not received training on the updated information. Patient #43: The EMR for Patient #43 was reviewed at approximately 1:47 PM on [redacted], and revealed a physician's history and physical exam dated [redacted]. Patient #43 was admitted with medical problems with menorrhagia with a past medical history of liver cirrhosis with a coagulation disorder and had been bleeding every day. Review of the Single Transfusion Record on [redacted], for Patient #43 revealed the following: Product: Leuko-Red RBC Start: [redacted] 5:42 PM End: [redacted] 6:00 PM Completed: [redacted] 5:07 PM Volume: 500 mL The Single Transfusion Record for Patient #43 had been altered two days after the transfusion had ended, which resulted in incomplete and inaccurate documentation of the blood transfusion.	A 385		

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A 385	Continued From page 68 The Single Transfusion Record, as entered, indicated that the 500 ml blood transfusion was completed in only 18 minutes, starting on [redacted], at 5:42 PM. and ending on [redacted], at 6:00 PM, according to the start and end date and times entered in the record. However the "Completed" time for the transfusion entered in the EMR was [redacted], at 5:07 PM, approximately 2 days after the transfusion was started. Review of the "Administration Details" (a separate area in the EMR) revealed that the transfusion began on [redacted], at 5:42 PM, and was actually stopped on [redacted], at 8:35 PM, which was a duration of 2 hours and 53 minutes. Administration Details: New Bag. Action Time: [redacted], at 5:42 PM, Recorded time: 5:44 PM, authenticated by RN with another RN dual signoff. Stopped. Action Time [redacted], at 8:35 PM., Recorded Time [redacted], at 8:35 PM, authenticated by RN. Stop Transfusion. Action Time: [redacted], at 6:00 PM. Recorded time [redacted], at 5:07 PM, authenticated by RN #10. Transfusion Vital Signs in the Single Transfusion Record included the following for [redacted]: At 5:42 PM - Temperature 97.9 F, Pulse 78,	A 385		

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A 385	Continued From page 69 Respirations 18, Oxygen Saturation 100%, Blood Pressure 119/53. At 6:00 PM- Temperature 97.9 F, Pulse 87, Respirations 16, Oxygen Saturation 99%, Blood Pressure 119/53. At 6:21 PM- Temperature 98.2 F, Pulse 80, Respirations 16, Oxygen Saturation 100%, Blood Pressure 102/46. End of Single Transfusion Record. However, review of the ED Narrator (log) in the EMR and the flowsheets elsewhere in the EMR revealed that Patient #43 was in the Emergency Department for the blood transfusion between 5:42 PM and 8:35 PM on [redacted]. Review of the EMR flowsheet revealed the following additional vital signs for [redacted]: At 7:38 PM - Temperature 98.4 F, Pulse 80, Respirations 23, Oxygen Saturation 100%, Blood Pressure 102/46. At 8:27 PM - Temperature 98.2 F, Pulse 79, Respirations 15, Oxygen Saturation 100%, Blood Pressure 159/64. At 9:00 PM- Temperature 97 F, Pulse 79, Respirations 18, Oxygen Saturation 100%, Blood Pressure 172/74. Vital signs were not obtained within 15 minutes after the transfusion was started at 5:42 PM, but were obtained at 6:00 PM, 18 minutes later. Vital	A 385		

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A 385	Continued From page 70	A 385		

signs were not obtained every hour per policy; vital signs were obtained at 6:21 PM. and not again until 7:38 PM, a gap of 1 hour and 17 minutes.

Review of the record revealed that the blood transfusion had apparently been stopped in the EMR on [redacted], at 8:35 PM, when the actual transfusion was completed. However, the blood transfusion EMR record had not been completed or "closed", resulting in continued monitoring and continued status as if the transfusion had not been completed. Until the record was "completed" in the EMR, the transfusion record continued, open for any nurse to make an entry.

On [redacted], at 5:07 PM, almost two days after the transfusion actually ended, RN #10 entered a "Stop Transfusion" time of [redacted], at 6:00 PM., thereby, altering the record to be inaccurate. When the entry was made by RN #10 on [redacted], the EMR system entered a stop time of [redacted], at 6:00 PM, which was not accurate.

The findings for Patient #43, the inaccurate end time of the transfusion, the missing vital signs, and the altered medical record were confirmed in an interview in the hospital conference room at approximately 1:47 PM. on [redacted], with RN #4.

An interview was then conducted with RN #10 at 16 Tower at 3:29 PM on [redacted], accompanied by RN #49, Nurse Manager, and RN #50, Nurse Director.

The blood transfusion record for Patient #43 was

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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 385	Continued From page 71 reviewed with RN#10, who stated, "I took care of this patient. In the medical record, it showed that the blood transfusion was still going [on [redacted], 2 days later]. I had to close the blood transfusion. I talked to the Educator and the Educator said, 'You need to end the blood transfusion.' I did that. I went in and ended the blood transfusion." When asked by the surveyor if RN #10 knew that ending the blood transfusion altered the transfusion record, RN #10 stated that she was unaware, that she simply went into the record and ended the blood transfusion in the record as she was told to do. When informed that the end time of the transfusion record was changed, RN #10 stated that she did not know, she was only ending the blood transfusion in the EMR. In a subsequent meeting with the CEO, CNO, and RN #37 (Information Technology), in the office of the CEO at 4:20 PM on January 10, 2019, the above findings for Patient #43 and the altered medical record were reviewed and confirmed. The findings included the following: Single Blood Transfusion records are not consistently ended and/or not completed in the EMR by a nurse when the actual transfusion is completed, which results in the transfusion record continuing to monitor as it is not closed. The ending date/time, if not entered, may be inaccurate. The ending date/time can be left open for days, over multiple shifts. If the Single Blood Transfusion record is not completed/ended at the time that the actual transfusion is completed/ended, the record can be altered, and in fact was altered, resulting in an inaccurate record for Patient #43.	A 385		

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A 385	Continued From page 72 Vital signs for blood transfusions and the volume of the blood component are not consistently documented in accordance with policy. The CEO, CNO, and RN #37 were unaware that the Single Blood Transfusion record necessitated both actions to complete the record and that the record could be altered at any point until the record had been ended and completed. Patient #41: The electronic medical record for Patient #41 was reviewed at approximately 10:04 AM on [redacted], and revealed a physician's history and physical exam dated [redacted]. Patient # 41 was admitted with abdominal pain status post hiatal hernia repair and sleeve gastrectomy on [redacted]. Review of the Single Transfusion Record for [redacted] for Patient #41 revealed the following: Product: Leuko-Red RBC Start: [redacted] 0231 (2:31 AM) End: [redacted] 0502 (5:02 AM) Completed: [redacted] 1148 (11:48 AM) Volume: [left blank - no documentation of volume] Transfusion Vital Signs logged in the transfusion record: At 2:31 AM. - Temperature 99.3 F, Pulse 125,	A 385		

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Respirations 18, Oxygen Saturation 96%, Blood Pressure 109/41.

At 2:46 AM - Temperature 99.9 F, Pulse 122, Respirations 23, Oxygen Saturation 95%. No Blood Pressure.

At 4:00 AM - Pulse 120, Respirations 21, Oxygen Saturation 96%. No Temperature and Blood Pressure.

At 5:0 AM0 - Temperature 99.9 F, Pulse 118, Respirations 25, Oxygen Saturation 94%. No Blood Pressure.

At 5:02 AM - Temperature 99.9 F, Pulse 123, Respirations 20, Oxygen Saturation 99%, Blood Pressure 130/65.

There was no Volume entered for the amount transfused. There was no blood pressure taken 15 minutes after the start of the transfusion and no blood pressure taken hourly until the transfusion ended.

There was no pulse, temperature, SPO2, or respiratory rate taken after 2:46 AM until 4:00 AM, which was a 1 hour and 14 minute gap. There was no evidence of the volume transfused.

The Single Blood Transfusion record was not "completed" in the EMR and was left opened in the EMR until [redacted], at 11:48 AM., over 2 days and 6 hours after the transfusion was actually completed.

Review of the Single Transfusion Record for

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A 385	Continued From page 74 [redacted], for Patient #41 revealed the following: Product: Leuko-Red RBC Start: [redacted] 2226 (10:26 PM) End: - blank - there was no end time recorded as of 11:56 AM on [redacted]. Completed: [redacted] at 1225 (12:25 PM) Volume: [left blank - no documentation of volume] There was no Volume entered for the amount transfused. There was no means to determine in the EMR when the blood transfusion was actually ended. The completed time, which was entered at 12:25 PM on [redacted], was 13 hours and 59 minutes after the start of the blood transfusion on [redacted], at 10:26 PM. The vital sign record for the blood transfusion continued to collect vital sign data for the blood transfusion record through [redacted], at 9:00 AM., as the transfusion had not also been ended in the EMR when observed by the survey team. There was no "Stop Transfusion" action time or recorded time in the EMR. The Single Blood Transfusion record was still capturing vital signs past the entered "Completed" time of [redacted], at 12:25 PM; a time was never entered for the end of the blood transfusion. The blood transfusion record was not ended as of the record review by the survey team on [redacted], at 10:04 AM, almost 3.5 days after the transfusion was started Transfusion Vital Signs documented in the transfusion record included:	A 385		

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A 385	Continued From page 75	A 385		

[redacted]

At 10:26 PM - Temperature 99 F, Pulse 120, Respirations 19, Oxygen Saturation 98%, Blood Pressure 176/66.

At 10:45 PM - Temperature 99 F, Pulse 122, Respirations 21, Oxygen Saturation 96%, Blood Pressure 168/78.

At 11:23 PM - Temperature 99.5 F, Pulse 120, Respirations 22, Oxygen Saturation 98%, Blood Pressure 174/71.

[redacted]

At 12:00 AM - Temperature 99 F, Pulse 120, Respirations 24, Oxygen Saturation 97%, Blood Pressure 150/76.

At 12:23 AM - Blood Pressure 136/74.

At 1:00 AM - Temperature 99 F, Pulse 125, Respirations 27, Oxygen Saturation 95%.

At 1:23 AM- Blood Pressure 146/64

At 2:00 AM - Temperature 99.6 F, Pulse 120, Respirations 29, Oxygen Saturation 96%, Blood Pressure 150/78

At 2:23 AM - Pulse 120, Oxygen Saturation 95%, Blood Pressure 122/49.

At 3:00 AM - Temperature 99.3 F, Pulse 123, Respirations 10, Oxygen Saturation 96%, Blood Pressure 135/50.

At 3:23 AM - Temperature 99.6 F, Pulse 124,

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Respirations 22, Oxygen Saturation 96%, Blood Pressure 140/75.

At 4:00 AM - Temperature 99.2, Pulse 127, Respirations 24, Blood Pressure 138/78.

At 4:23 AM - Blood Pressure 154/83.

At 5:00 AM - Temperature 98, Pulse 125, Respirations 26, Oxygen Saturation 92%, Blood Pressure 160/80.

At 5:33 AM - ...

The vital signs continued to be logged as above in the "Single Transfusion Record".

There was no temperature, pulse, respiratory rate, or SPO2 documented on the patient 15 minutes after the transfusion was started, until 10:45 PM, 19 minutes later. Vital signs are required 15 minutes after the start of a transfusion. The temperature was not documented after 5:00 AM on [redacted], presumably because the transfusion should have ended by then; the next temperature was documented at [redacted], at 12:00 AM.

In an interview with RN #4 at approximately 10:04 AM on January 10, 2019, in the hospital conference room, RN #4 stated, "There was no end date entered and the blood transfusion record is still capturing information." RN #4 stated that the EMR has "an option to 'Stop' or to 'Stop and Complete' by the nurse. If there was a transfusion reaction, the record would stop, but not complete. This record was completed, but not

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ended, so it is still going. So we [nurses] need training on that." When asked by the surveyor when this transfusion actually ended, RN #4 was unable to determine based on available information in the EMR.

The above findings for Patient #41, including vital signs not taken per policy and protocol, lack of volume of blood transfusion documented, and transfusion records not ended or completed in the EMR, were confirmed in an interview in the hospital conference room at approximately 10:12 AM on [redacted], with RN #4.

Patient #45:

Review of the medical record for Patient #45 was conducted at approximately 10:22 AM on [redacted] and revealed a physician's history and physical exam dated [redacted]. Patient #45 was admitted with acute renal failure, life threatening hypotension during dialysis which resulted in a code. She was intubated and coded a second time from hypotension during hemodialysis. An EGD revealed a bleeding gastric ulcer requiring blood transfusion. Patient #45 had diagnoses of acute combined systolic and diastolic congestive heart failure, recurrent right pleural effusion, acute and chronic renal failure, volume overload, hypotension, and shock/circulatory.

Review of the Single Transfusion Record on [redacted], for Patient #45 revealed the following:

Product: Leuko-Red RBC
Start: [redacted] 1723 Dual signoff completed.

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A 385	Continued From page 78 End: [redacted] 2041 (8:41 PM) Completed: [redacted] 1015 (10:15 PM) Volume: 350 mL The comment, "Please transfuse over 4 hours." was entered with the order from [redacted] at 4:54 PM in the EMR. Review of the Single Transfusion Record revealed that the transfusion occurred over 3 hours and 18 minutes, 42 minutes quicker than ordered. Review of the medical record with RN #4 revealed no nursing documentation related to or explaining the shorter infusion time of 3 hours and 18 minutes, when the ordered comment stated to transfuse over 4 hours. The Single Transfusion Record in the EMR for this transfusion was not completed until [redacted], at 10:15 AM, which was over 3 and a half days after the transfusion ended. Transfusion vital signs included: [redacted] At 5:22 PM - Temperature 99.5 F, Pulse 88, Respirations 20, Oxygen Saturation 100%, Blood Pressure 135/59. At 5:33 PM - Blood Pressure 145/45. At 5:37 PM- Temperature 99 F, Pulse 92, Respirations 16, Oxygen Saturation 100%, Blood Pressure 145/45. At 6:00 PM- Temperature 98.7 F, Pulse 90, Respirations 20, Oxygen Saturation 100%, Blood	A 385		

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A 385	Continued From page 79	A 385		

Pressure 151/63.

At 7:00 PM- Temperature 98.9, Pulse 81, Respirations 19, Oxygen Saturation 98%, Blood Pressure 139/51.

At 7:02 PM - Blood Pressure 139/51

At 7:22 PM - Pulse 88, Respirations 19, Oxygen Saturation 98%.

At 8:00 PM- (Pain Assessment only, no vital signs)

At 8:40 PM- Temperature 99.5 F, No Pulse, no Respirations, No Oxygen Saturation, No Blood Pressure.

At 8:41 PM- Temperature 99.5 F, Pulse 73, Respirations 15, Oxygen Saturation 100%, Blood Pressure 113/55

There was no temperature taken between 7:00 PM. and 8:40 PM, a gap of 1 hour and 40 minutes during the transfusion.

There was no pulse between 7:22 PM. and 8:41 PM., a gap of 1 hour and 19 minutes.

There was no respiratory rate between 7:22 PM and 8:41 PM, a gap of 1 hour and 19 minutes.

There was no oxygen saturation between 7:22 PM and 8:41 PM, a gap of 1 hour and 19 minutes.

Review of the Single Transfusion Record for

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A 385	Continued From page 80 [redacted] for Patient #45 revealed the following: Product: Leuko-Red RBC Start: [redacted] 1:14 PM Dual signoff completed. End: [redacted] 4:30 PM Completed: [redacted] 4:58 PM Volume: 350 mL Transfusion Vital Signs included: [redacted] At 1:14 PM - Temperature 97.6 F, Pulse 68, Respirations 14, Oxygen Saturation 100%, Blood Pressure 120/45. At 1:30 PM - Temperature 97.7 F, Respirations 14 , Oxygen Saturation 100% , Blood Pressure 131/50. No Pulse. At 2:00 PM - Pulse 70, Respirations 13 , Oxygen Saturation 100%. No Temperature and no Blood Pressure. At 2:30 PM - Temperature 97.5 F, Respirations 14, Oxygen Saturation 100%, Blood Pressure 126/49. No Pulse. At 3:00 PM - Pulse 69, Respirations 12, Oxygen Saturation 100%. No Temperature, no Blood Pressure. At 4:00 PM- Pulse 78, Respirations 12, Oxygen Saturation 100%. No Temperature, no Blood Pressure. At 4:26 PM- , Pulse 71, Oxygen Saturation 100%. No Temperature, no Blood Pressure, no	A 385		

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Respirations.

At 4:30 PM - Temperature 97.6 F, Pulse 69, Respirations 15, Oxygen Saturation 100%, Blood Pressure 117/44.

The pulse was not obtained after the transfusion started until 2:00 PM, a gap of 46 minutes. The temperature was not obtained between 2:30 PM and 4:30 PM, when the transfusion was ended, a gap of 2 hours.

The blood pressure was not obtained between 2:30 PM and 4:30 PM, when the transfusion was ended, a gap of 2 hours.

Review of the Single Transfusion Record for [redacted] for Patient #45 revealed the following:

Product: Leuko-Red RBC
Start: [redacted] 1114 (11:00AM) Dual signoff completed.
End: [redacted] 1407 (2:07 PM)
Completed: [redacted] 1408 (2:08 PM)
Volume: 355 mL

Transfusion Vital Signs included:
[redacted]

At 11:14 AM - Temperature 97.1 F, Pulse 76, Respirations 15, Oxygen Saturation 100%, Blood Pressure 140/63.

At 11:46 AM - Temperature 96.6 F. No Pulse, no Respirations, no Oxygen Saturation, no Blood

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Pressure.

At 12:00 PM - Pulse 76, Respirations 16 , Oxygen Saturation 100%, Blood Pressure 128/52. No Temperature.

At 1:00 PM - Pulse 76, Respirations 19, Oxygen Saturation 100%, Blood Pressure 127/53. No Temperature.

At 2:00 PM - Pulse 75, Respirations 16, Oxygen Saturation 100%, Blood Pressure 128/53. No Temperature.

At 2:07 PM - Temperature 96.7 F, Pulse 75, Respirations 16, Oxygen Saturation 100%, Blood Pressure 131/54.

Vital signs were not taken 15 minutes after the transfusion was started per policy as the vital signs were taken at 11:14 AM and not taken again until 11:46 AM, a gap of 32 minutes.

The pulse was not taken 15 minutes after the transfusion was started. The pulse was taken at 11:14 AM and 12:00 PM, a gap of 47 minutes.

There was no temperature taken between 1146 and the end of the transfusion at 2:07 PM, a gap of 2 hours and 21 minutes.

The findings for Patient #42 were confirmed in an interview in the hospital conference room at approximately 10:22 AM on [redacted] with RN #4.

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A 385	Continued From page 83 Patient #39: The electronic medical record for Patient #39 was reviewed at approximately 9:30 AM on [redacted], with RN #4 in the hospital conference room and revealed a physician's history and physical exam dated [redacted]. Patient #39 was admitted with a history of seizures, CVA, progressive claudication in the left leg, sepsis, gangrene of toe of left foot, and acute renal failure. Hemoglobin on admission was 9.0 gm/dL. Review of the Single Transfusion Record on [redacted] at 9:40 AM for Patient #39 revealed the following: Product: Leuko-Red RBC Start: [redacted] at 0940 (9:40 AM) End: [redacted] at 1200 (12:00 PM) Completed: [redacted] at 1211 (12:11 PM) Volume: 350 mL Transfusion Vital Signs included: At 9:15 AM - Temperature 97.6 F, Pulse 74, Respirations 18, Oxygen Saturation 96%, Blood Pressure 119/57. At 9:46 AM- Pulse 84, Respirations 16, Oxygen Saturation 97%. No Temperature, no Blood Pressure. At 9:51 AM- Temperature 97.6 F, Pulse 85, Respirations 18, Oxygen Saturation 97%, Blood Pressure 129/59. At 10:42 AM- Temperature 97.4 F, Pulse 79, Respirations 18, Oxygen Saturation 95%, Blood Pressure 138/59.	A 385		

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A 385	Continued From page 84 At 12:00 PM- Temperature 97.5 F, Pulse 83 , Respirations 18, Oxygen Saturation 97%, Blood Pressure 134/65. There was no temperature taken 15 minutes after the transfusion was initiated; the patient's temperature was not taken after the transfusion was initiated until 36 minutes after the transfusion was initiated. There was no blood pressure taken 15 minutes after the transfusion was initiated; the patient's blood pressure was not taken after the transfusion was initiated until 36 minutes after the transfusion was initiated. Vital signs were not documented every hour during the blood transfusion as there were no vital signs documented between 10:42 AM and 12:20 PM., a gap of 1 hour and 18 minutes. Review of the Single Transfusion Record on [redacted], at 1:18 PM. for Patient #39 revealed the following: Product: Leuko-Red RBC Start [redacted] at 1318 (1:18 PM) End [redacted] at 1613 (4:13 PM) Completed [redacted] at 1613 (4:13 PM) Volume: [left blank - no documentation of volume] Transfusion Vital Signs included: At 1:14 PM - Temperature 98.2 F, Pulse 85, Respirations 18, Oxygen Saturation 96%, Blood	A 385		

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Pressure 143/69.

At 1:39 PM- Temperature 98 F, Pulse 88, Respirations 18, Oxygen Saturation 95%, Blood Pressure 131/69.

At 2:51 PM - Temperature 98.2 F, Pulse 82, Respirations 18, Oxygen Saturation 97%, Blood Pressure 137.63.

At 4:13 PM - Temperature 97.6 F, Pulse 81, Respirations 18, Oxygen Saturation 96%, Blood Pressure 132/64.

There was no Volume entered for the amount transfused.

Vital signs were not obtained within 15 minutes of initiating the transfusion, as vital signs were taken 21 minutes after initiation.

Vital signs were documented at 1:39 PM and not again until 2:51 PM, which is a gap of 1 hour and 12 minutes.

Vital signs were documented at 2:51 PM and not again until 4:13 PM, which is a gap of 1 hour and 22 minutes.

The findings for Patient #39 were confirmed in an interview in the hospital conference room at approximately 9:30 AM on [redacted], with RN #4.

Patient #40:

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A 385	Continued From page 86 The electronic medical record for Patient #40 was reviewed at approximately 2:55 PM on [redacted]. Review of the Single Transfusion Record for Patient #40 on [redacted], revealed the following: Product: Leuko-Red RBC Start: [redacted] 2331 (11:31 AM) End: [redacted] 0242 (2:42 AM) Completed: [redacted] 0244 (2:44 AM) Volume: 700 mL Transfusion Vital Signs included: At 11:31 PM- Temperature 97.7 F, Pulse 94, Respirations 18, Oxygen Saturation 98%, Blood Pressure 133/70. At 11:45 PM- Temperature 97.7 F, Pulse 72, Respirations 18, Oxygen Saturation 99%, Blood Pressure 126/67. At 12:45 AM- Pulse 61, Respirations 18, Oxygen Saturation 99%, Blood Pressure 116/61. No Temperature. At 1:45 AM- Pulse 66, Respirations 17, Oxygen Saturation 100%, Blood Pressure 123/67. No Temperature. At 2:42 AM - Temperature 97 F, Pulse 60, Respirations 17, Oxygen Saturation 98%, Blood Pressure 116/62. There was no temperature taken between 11:45 and 2:42 AM, which is a gap of 2 hours and 57 minutes.	A 385		

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A 385	Continued From page 87 The findings for Patient #40 were confirmed in an interview in the hospital conference room at approximately 2:55 PM on [redacted], with RN #8. Patient #42: The medical record for Patient #42 was reviewed at approximately 1:47 pm on [redacted] and revealed a physician's history and physical exam dated [redacted]. Patient #42 was admitted with a history of pulmonary embolism and shortness of breath. Discharge summary on [redacted] revealed that Patient #42 had acute anemia with chronic saddle pulmonary embolus. Review of the Single Transfusion Record on [redacted] for Patient #42 revealed the following: Blood transfusion 1/7/19 Product: Leuko-Red RBC Start: [redacted] 1033 End: [redacted] 1345 Completed: [redacted] 1347 Volume: [left blank - no documentation of volume] There was no Volume entered for the amount transfused. The findings for Patient #42 were confirmed in an interview in the hospital conference room at approximately 1:47 pm on [redacted] with RN #4. Facility policy provided to the survey team,	A 385		

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"Transfusion of Blood Products-Patient Care", effective date May 2018, stated, in part,

"POLICY ...L. Transfusion reactions can be life-threatening and occur with exposure to even a small amount of blood; therefore, transfusions should be started slowly unless the patient's condition requires a rapid, life-sustaining transfusion. Baseline vital signs should be obtained within 60 minutes of initiation of the transfusion, and should be reassessed at the end of the first 15 minutes, every hour, and when the transfusion is complete ...

PROCEDURES: (NON-OPERATING ROOM AREAS)

1. A physician's order is required for the transfusion of blood and blood products.

a. The physician will enter the order into the electronic medical record (EMR).

b. The order will specify the type of blood product, quantity, and indication for transfusion ...

3. Assessment Before Transfusion ...

b. Verify physician's order for blood products ...

f. Assess vital signs, including blood pressure, heart rate, respiratory rate, oxygen saturation and temperature. (Initial vital signs must be within the previous 15 minutes) ...

4. Administration Process ...

l. Check vital signs 15 minutes after making

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any connection. (Initial vital signs must be within the previous 15 minutes) ...

n. Unless the patient requires a rapid, life-sustaining transfusion, infuse slowly for the first 15 minutes while observing the patient for adverse reactions as described below.

o. After 15 minutes, if no signs of a transfusion reaction are noted, reassess vital signs and increase the flow rate to the desired speed. Infusion time should not exceed 4 hours. The longer the blood is left at room temperature, the greater the danger of bacterial proliferation and RBC hemolysis.

p. Monitor vital signs and assess temperature and urine throughout the transfusion process to monitor for adverse reactions to blood products and the effectiveness of treatment. Vital signs are done every hour, and when the transfusion is complete.

q. Monitor for signs and symptoms of transfusion reactions. Both acute and delayed hemolytic reactions are potentially life-threatening events."

Facility policy provided to the survey team, "Transfusion of Blood Products-Patient Care", effective date May 2018, stated, in part,

"Appendix A

CHI Baylor St. Luke's Massive Transfusion Protocol

Activated by bedside physician for patients with:

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A 385	Continued From page 90 4 units PRBC in 1 hour or large volume bleeding 1. CALL Page Operator ... 2. CALL Transfusion Service ... 3. Place order in EPIC for MTP (Massive Transfusion Order Set) ... 4. Send runner to Transfusion Service WITH patient ID label ..." Transportation of blood products by staff : Resident #65: Record review of an incident that occurred on 10/19/2018 revealed, the nursing staff requested for a "STAT" blood unit to the main laboratory at 1:51 PM. A carrier was assigned to pick up the blood. The carrier arrived to the patient unit at 4:00 PM. When the nurse asked the carrier why it took two hour to deliver the blood the carrier stated "I have other pickups to get first". The patient was in the intensive care unit due to a critical gastro-intestinal bleeding. On January 9, 2019, at 11:00 AM, the hospital CNO (Chief Nursing Officer) was interviewed. The CNO stated that a carrier or runners can be any staff available. When asked if the carriers or runners have been trained on the significance of picking up blood from the blood bank the CNO stated "I don't believe there is a training". The CNO confirmed that the hospital did not have a policy and procedure on who can pick up blood from the blood bank.	A 385		

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On January 9, 2019, at 2:15 PM, an interview was conducted with the hospital CNO. The CNO stated she was not aware that the problem with nurses compromising the type and screen blood tube by not providing a clear label and patient information to the blood bank was still unresolved.

On January 9, 2019, at 4:00 PM, the hospital CEO (Chief Executive Officer) was interviewed concerning who can pick up blood from the blood bank and deliver to the nursing units. The CEO stated a runner. The CEO stated that a runner is any staff available at the time of the need for flood transfusion. The CNO confirm that currently there is no a training available for the runners (carriers) neither a hospital policy and procedure that address who can pick up blood from the blood bank and deliver it to the nursing units.

On January 10, 2019, at 9:45 AM, an interview with the hospital Acting Chief Medical Officer (ACMO) was conducted. During the interview, the ACMO stated that he did not know that the hospital did not had a formal training for the "carriers/runners that pick blood products from the Blood Bank. The ACMO indicated that a training will have to be develop as soon as possible.

On January 10, 2019, at 11:30 AM, the Director/Training and Nursing Education & Research was interviewed. During the interview the director stated that only nurses can pick up blood products from the Blood Bank. The director was not aware that the hospital had carriers/runners picking up blood products to be transfuse. The director confirmed that the

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A 385	Continued From page 92 hospital did not have training establish for runners/carriers related to picking up blood from the blood bank. On January 10, 2019, at 4:10 PM, the CEO indicated that the hospital is going to start training for carriers/runners assigned to pick up blood products from the Blood Bank. Review of incidents related to blood sample for type and screen: Record review of the hospital incident Log from September 2018 to January 8, at 12:00 PM revealed that the nursing staff attempted to submit blood samples to the Blood Bank for patient type and screen 122 times. The Blood Bank rejected the 122 specimens indicating "Blood specimen received in Transfusion Services without a date and time entered in EPIC system. Final verification of patient identity had not been completed receipt of the specimen. Therefore, patient identity is uncertain. Specimen was rejected for testing and a recollection/redraw was enter in EPIC". Record review of the hospital incident log after [redacted], showed 21 blood tubes for type and screen were mislabeled or double labeled. The Blood Bank rejected all 21 samples. Record review of the hospital incident log from January 1, 2019, to January 9, 2019, showed 17 blood tubes for type and screen were mislabeled and 1 was double labeled.	A 385		

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A 385	Continued From page 93 On January 10, 2019, at 10:30 AM, an interview with the Quality Assessment and Performance Improvement (QAPI) Director was conducted. The QAPI Director stated that after the incident in [redacted], the hospital developed new training for nurses. The training was focused on preventing errors when drawing blood sample for type and screen, labeling of the specimen, and drawing 2 specimens if the patient did not have a history of a type and screen at the hospital. The director stated, "The patient will have one blood sample for type and screen with the correct date and time and double label, if the patient does not have a current type and screen for blood products we will wait for the blood bank to give us the result and we will do a second blood type and screen to verify the results of the first sample". The QAPI Director indicated that the nurses are not to send patient blood tubes for type and screen if the label is compromised. When asked who was monitoring the QAPI plan to ensure that the incidents of the blood bank rejecting sample due to a compromised label are reducing based on the training that was provided to the nurse the QAPI director stated, "We have not been monitoring the plan". The director stated that when the blood bank reject the blood sample for type and screen the patient will have to wait longer if blood products need to be transfuse. On January 10, 2019, at 5:00 PM the hospital CEO was interviewed concerning the pattern of mislabels on blood tubes to be type and screen. The CEO stated it should be zero. "These are patients life and blood is important". The CEO stated that they will have to retrain all the nurses to ensure that there are no mislabels of blood sample tubes. The CEO stated, "This is	A 385		

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A 385	Continued From page 94 unacceptable". The review of the hospital's 2018 Blood Transfusion Overview Training provided to the nursing staff during orientation period and annually showed the individual collecting the blood sample must ensure the labels in the blood tubes are clear, legible, time and dated, verify the correct patient with two identifiers the computer generated label and the patient identification band. Record review of the hospital's incident log from September 2018 to January 8, 2019 revealed the nursing staff attempted to submit blood samples to the Blood Bank for patient type and screen 122 times. The Blood Bank rejected the 122 specimens indicating "Blood specimen received in transfusion services without a date and time entered in EPIC system. Final verification of patient identity had not been completed receipt of the specimen". Therefore, patient identity is uncertain. Specimen was rejected for testing and a recollection/redraw was enter in EPIC". On January 10, 2019, at approximately 9:50 AM an interview was conducted with the hospital CEO, ACMO, CNO, Laboratory Director, QAPI Director, and Training /Education & Research Director was conducted. During the interview, the survey team discussed the number of time the nursing staff attempted to submit blood specimen to the Blood Bank with mislabels, unclear time, date of collection, and double label. The Blood Bank rejected the specimens. It was asked who was monitoring the number of incidents after [redacted]. The hospital leadership stated, "We are only documenting at this time, we have not been monitoring the incidents."	A 385		

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RN #4 stated that there was no place to document in the EMR who transported the blood or blood components from the blood bank to the nurse on the unit responsible for the transfusion. This presents a lack of tracking of the blood component, including the amount of time for transporting the specimen, and the control or location of the blood or blood component at all times.

RN #4 stated that the time the unit [blood component] is picked up from the blood bank is not in the EMR and the time the unit arrives on the unit is not captured in the EMR. RN #4 stated, "I'm unsure what happens to the blood between pickup from the blood bank and arrival to the nurse; it's not documented anywhere."

An interview was conducted on 10 Tower at 10:49AM on January 9, 2019, with RN #2. When asked by the surveyor which staff can pick up blood products from the blood bank for delivery to the unit, RN #2 stated, "Anybody. A runner, secretary, or the nurse can go and get the blood. Usually it's a PCA or nurse, but there are situations where the secretary can go and get the blood."

An interview was conducted on 10 Tower at 11:23 AM on January 9, 2019, with Unit Secretary #1. When Unit Secretary #1 was asked by the surveyor if she had ever picked up blood for a patient from the Blood Bank, Unit Secretary #1 stated, "Yes." Unit Secretary #1 stated she last picked up blood from the Blood Bank "about 6 weeks ago, usually it's when it gets busy."

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An interview was conducted with RN #9 on 14 Tower at 3:00 PM. on January 9, 2019. When asked by the surveyor which staff could pick up blood from the blood bank, RN #9 stated, "We delegate to a Patient Care assistant (PCA) or whoever is available. The PCA and the secretary can pick up blood."

An interview was conducted with the Blood Bank Director in the hospital conference room at 1:24 PM. on January 9, 2019. When asked by the survey team if a unit secretary could pick up blood from the blood bank, the Blood Bank Director stated, "No."

Transfusion Reaction Alerts:

An interview was conducted on 10 Tower at 10:49 AM on January 9, 2019, with RN #2. When asked by the surveyor what happens if a patient begins having a transfusion reaction, RN #2 stated, "They will have an increased temperature, fever, chills, low flank pain, a rash. If there is any change in the vital signs, EPIC will trigger a sepsis alert ...EPIC will alarm if there is an increased temperature, if the blood pressure spikes, O2 sat, respirations increase or the heart rate increases." When asked to confirm the EPIC alerts, RN #2 repeated that EPIC would alert for changes in temperature, blood pressure, oxygen saturation, respirations, and pulse.

An interview was conducted with RN #9 on 14 Tower at 3:00 PM on January 9, 2019. When asked by the surveyor if the electronic medical record system provided alerts for transfusion reactions, RN #9 stated, "I think there are alerts.

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Temp 2 degrees above or below, blood pressure about 20 positive or negative, O2 sat would alert, respirations would alert."

An interview was conducted with RN #6, January 7, 2019, at 11:25 AM in the Coronary Care unit (CCU). When asked by the surveyor how a nurse would know if a patient was having a transfusion reaction, RN #6 stated, "The system [EMR] has alerts due to vital signs of a possible transfusion reaction." When asked how a possible transfusion reaction would be managed, RN #6 stated, "We would notify blood bank, send them the tubing, and we would get a template from Quality."

The above findings regarding a lack of understanding of the EMR alerts during a blood transfusion was confirmed in an interview with the CEO and the CNO at 4:20 PM. on January 10, 2019, in the office of the CEO.

Registered Nurse Education and Training Review:

On January 10, 2019, at 11:00 AM, hospital registered nurse's personnel files were reviewed; 2 of 39 registered nurses (RN #32 and RN #37) did not have blood transfusion training. This failed practice has the potential to affect patients receiving blood transfusion.

RN #32: The RN was assigned to work in the emergency department on December 12, 2018. According to emergency department director (RN#33), RN #32 has until February 2019 to complete the training. The director stated that

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A 385	Continued From page 98 RN #32 is in the preceptor program and she is not expected to do blood transfusion by herself. When asked if RN #32 should have been trained due to the adverse blood reaction can occurred at any time during the blood transfusion. The director stated "yes she should have taken this training after we have the event on [redacted], [redacted]". RN #37: The RN was assigned to the Information Technology Department (IT). The personnel file review confirmed RN #37 does not have the blood transfusion training. On January 10, 2019, at 11:30 AM an interview was conducted with the Education/Training Director. The director stated that RN #37 does not need the training because he sometimes teach the blood transfusion class. When asked if he has done any blood transfusion training since the incident in [redacted]. The director stated "probably not".	A 385		