[redacted]

From: [redacted] <[redacted]sharinghopesc.org>
Sent: Wednesday, January 16, 2019 6:29 PM
To: [redacted]
Cc: [redacted]
Subject: SHSC (SCOP) and Grand Strand Regional Hospital Root Cause Analysis [redacted]
Attachments: RCA UNOS ABO Incompatibility SHSC and GSRH 01.16.19.pdf; Grand Strand Regional Hospital Policy Letter 01.16.19.pdf

[redacted]

Attached you will find the **preliminary** write up from the RCA conducted on January 10, 2019 between SHSC (SCOP) and Grand Strand Regional Hospital regarding Donor [redacted] This write up includes the working corrective action plan from SHSC. Attached is also a letter from Grand Strand Regional Hospital stating that they followed their policies regarding ABO typing in this donor. If you have any questions, please feel free to contact either [redacted] or me. As I stated in the previous email I will be out of the office until next Wednesday January 23, 2019.

[redacted]

[redacted]
Director Quality Systems

We Are Sharing Hope SC
[redacted]

Give the Gift of Life
Register to Be an Organ Tissue Donor at http://www.DonateLifeSC.org

We Are Sharing Hope SC
Root Cause Analysis (RCA) Worksheet and CAP

NCR#

Date of Event: 11/24/2018	Day of the week: Saturday	Time: 21:08
Donor ID# [redacted]	UNOS ID# [redacted]	Department(s): Clinical Recovery Services/ Grand Strand Regional Hospital

Date of RCA Meeting: 01/10/2019 Event Type: ABO incompatibility
Attendance: [redacted]
Was the event reported to an external agency: Yes
Name of Agency: UNOS /AOPO Date Reported: 11/28/2018- UNOS 11/29/18 AOPO

Define the Event: (What happened, when did it occur, who was involved, what was the outcome, what steps in the process were affected)

Event Details: [redacted] admitted 11/24/18, post motorcycle vs tree accident who sustained multiple significant injuries including Grade 1 liver laceration, fracture with deformity of right upper extremity, cerebral edema with downgoing transtentorial and tonsillar herniation incompatible with life. Emergently taken to the OR where she received approximately 7 units PRBC, 6 units FFP , 2 units of pooled platelets intraoperatively with O negative blood. ABO samples obtained post transfusion on 11/24/18 23:09 and 11/25/18 19:50, both indicating donor as O negative. The donor was classified as increased risk due to hemodilution using the PHS Increased Risk Disclosure Classification. After authorization for donation was obtained from next of kin, blood work for serology was sent to VRL Lab which results were determined to be "INDETERMINATE". Given that the two hospital ABO were drawn at different interval and the donor was acknowledged as "High Risk" allocation of the organs was initiated based on the O negative ABOs. Organ were allocated to:
HEART: NCCM
LUNGS: SCMU
LIVER: TNVU
PANCREAS: WIUW
INTESTINE: No list run, 209 (Multiple pressors)
KIDNEYS: 1 & 2 to SCMU
Donor was taken to the OR on 11/27/18 at 07:00 with cross clamp at 09:30- all allocated organs were recovered and transported to accepting centers.

11/28/18 at 00:52 the SHSC Communication Center received a call from transplant coordinator at WI in reference to the donor blood typing. The call was referred to the Organ AOC. The AOC spoke with the coordinator a t WI who indicated they has tested the blood they received with the pancreas and the ABO came back "A". WI stated that based on the ABO findings that declined and would discard the pancreas. OAOC began contacting the other transplant program for an update on the status of the other organ recipients. The lung recipient was doing poorly and showing signs of ABO incompatibility. The heart recipient had been placed on ECMO post-transplant and was also doing poorly consistent with ABO incompatibility. The left kidney recipient was doing well. The right kidney had not been transplanted, so the center was declining and would discard the right kidney given the situation with the ABO. The liver recipient was doing well. MUSC Blood Bank re-ran a sample at 11/28/18 which results indicated A negative. In addition, Anti-A titers in the lung recipient were elevated consistent with an ABO incompatible reaction.

Containment Plan

Indeterminate ABO typing- if blood typing results - for any test - indicates that the sample results are indeterminate- SHSC will immediate place further management of the case on "Hold" until the Administrator on call (AOC) and the Medical Director discuss the test results and decide how to proceed. This discussion will be documented in the donor medical record.

Patients on Massive Transfusion Protocols- if a patient who is being assessed and/or managed as a donor is/or has been on a massive transfusion protocol, SHSC will immediate place further management of the case on "Hold" until the Administrator on call (AOC) and the Medical Director discuss the how to proceed and the impact of ABO results. This discussion will be documented in the donor record.

01/10/2019- RCA Update of Case Review:

An initial ABO typing sample was obtained in the Emergency Department prior to the start of the massive transfusion protocol initiation, but was hemolyzed so another sample was requested by the Blood Bank. This sample was obtained on 11/24/18 at 23:09. This sample was run on the Ortho- Vision Analyzer. The results indicated an indeterminate results so the Technician ran a forward and reverse testing which indicated the forward results were "O" and the reverse of "A". "O" negative was reported as the ABO type from this sample since it is the hospital policy that the forward results indicate the red blood cells and reverse could be impacted by the fresh frozen plasma a patient receives in massive transfusion protocol. The sample drawn on 11/25/2018 at 19:50 was requested by the Blood Bank because the patient had been re-branded with a new ID representing her actual name which was not initially know in the Emergency Department. It is Grand Strands policy that when a patient is re- branded with a new ID band a new type and hold is drawn. This sample indicated a forward of "O" negative and reverse of "O" negative. The results were reported as "O" negative.

In discussion with the Blood Bank Supervisor and Technician present during the RCA- he stated that Grand Strand Regional Hospital was comfortable with the results obtained from the Ortho- Vision machine because the machine will detect the "double cell" so it is specifically used during cases of hemodilution.

Policies and Procedures

Please list the policies and procedure related to this event:
O1.110 Specimen Drawn for Donor Evaluation

O1.110-5 CAT ABO Verification form
O 3.031 Organ Allocation
O 3.033 Communication of Increased Risk Factor
O 3.033-1 Increased Risk Disclosure

NOTE: Grand Strand Regional Hospital could not share their policies due to the proprietary nature of HCA policies, we are not permitted to send the policies outside of our organization.

RCA Questions

HUMAN FACTOR		
	What was the human error? (fatigue, personal problem, stress, cognitive errors?	**None- There were no human factors identified that would impact this event.**
	What role did human performance play in these events, if any?	**None**
	Were distractions or interruptions a factor in these events?	**No**

COMMUNICATION AND DOCUMENTATION		
	Were there any delays in receiving the information?	**There was a delay in receiving information specifically ABO typing results but it is the policy of Grand Strand Regional Hospital that "indeterminate" results are not reported, the forward results are reported.**
	Are there obstacles to communication related to this event?	**None**
	Was the necessary information available, accurate and complete?	**The indeterminate results are maintained in the Blood Bank.**

Staffing , Training and Competency		
	Were issues related to staff training or competency a factor in the event? Is	**None- the SHSC CDC and CAT involved in this case have been trained and are competent to complete the required task related to ABO typing and organ allocation.**

	training provided prior to the start of the work process?	**Grand Strand Regional Blood Bank staff- have been trained and are competent to conduct ABO typing.**
	How is competency assessed post training? Are the competencies documented and where is the documentation located?	**Not relevant**
	Are the result of training monitored and assessed in relation to this event?	**Not relevant**
	Was staffing a factor in any of the identified errors?	**No**

Equipment		
	What equipment/products were involved in this event?	**Ortho- Vision Analyzer**

Policies and SOP		
	Is there a policy/SOP related to this event?	**SHSC- there are several policies related to specimen drawn for donor evaluation, ABO Verification and organ allocation.** **Grand Strand Regional Hospital has policies related to ABO testing, indeterminate results test and reporting ABO results:** **NOTE: Due to the proprietary nature of HCA policies, they are not permitted to send the policies outside of our organization.**
	Did the staff involved follow the policy /SOP as outlined?	**SHSC- Yes** **Grand Strand Regional Hospital- Yes**
	Were the staff involved aware of the policies/SOP?	**SHSC- Yes** **Grand Strand Regional Hospital- Yes**
	Are regulatory policies or guidance related to this event? Were they followed?	**UNOS and CMS has related policies to ABO typing each of which were followed.** **Grand Strand Regional Hospital- none identified**

Task/Process Factors		

	Are there redundancies within the process that should have eliminated the event from occurring?	**It was discussed that if both Grand Strand Regional Hospital results and VRL Laboratories results were both reported as indeterminate this would have been a "red" flag.**
	Were the workflows sufficient to prevent event from occurring?	**The establish workflows within the Blood Bank would not have impacted the event within the limits of the hospital setting. The workflow does impact the donation arena where ABO typing is used to match a recipient.**

GSRH Blood Bank		
	Were there any deviations in the testing of the ABO in this donor (patient)?	**None based on Grand Strand Regional Hospital policies.**
	Is hemodilution/massive transfusion considered when testing ABO typing?	**Yes- that is when the Orth-Vision Analyzer is used due to the sensitivity of the machine to "double cells".**
	The indeterminate results were not reported but the sample was re-run is this a standard procedure?	**Yes- the hospital policy that the forward results indicate the red blood cells and reverse could be impacted by the fresh frozen plasma a patient receives in massive transfusion protocol.**
	Are indeterminate results reported?	**No- it is the hospital policy to report the forward test results and not the indeterminate.**

SHSC Indeterminate Results		
	What is the process and communication for indeterminate typing results? Is this in policy or a practice?	**SHSC did not have a clear process for when an indeterminate results was communicated beside either drawing another sample or checking for an available sample at the time of this event.**
	What is the escalation process for contacting the medical director? Is this in policy or practice?	**SHSC did not have a clear process for when an indeterminate results should escalated at the time of this event.**

Management/		

Supervisory workforce factor		
	Was management made aware of the event timely?	**SHSC- Yes – the CEO was notified immediately.** **Grand Strand Regional Hospital- SHSC CEO contacted the hospital's CEO immediately.**

Other		
	Are there any other factors that could have influenced this event?	**None identified.**
	What other areas or services are impacted or might have a similar event?	**National discussion of these types of events and communication of any corrective actions.**

ROOT CAUSE ANALYSIS

RCA /Event Type	What was the root cause of the event
	The hospital's process reporting of ABO typing and indeterminate results does not directly impact the patient who is receiving the massive transfusions, but does have an impact of the donor allocation process and recipients. **Both SHSC and Grand Strand Regional Hospital followed their specific policies both internally and national regulatory policies. The present nature of procedures for massive transfusions, use of "A" blood type fresh frozen plasma and the impact on ABO typing is not recognized in both the hospital Blood Bank process and donation arena process for allocation.**

Literature Search: Cite any books, journal articles, and standards that were used or considered in developing the root cause and CAP.
Literature search did not reveal any relevant books, journal articles and standards regarding massive transfusion, hemodilution, ABO typing and organ allocation.

Corrective Action Plan and Monitoring
Containment Plan
Indeterminate ABO typing- if blood typing results - for any test - indicates that the sample results are indeterminate:

- SHSC will immediate place further management of the case on "Hold" until the Administrator on call (AOC) and the Medical Director discuss the test results and decide how to proceed.
- The Medical Director will contact the Blood Bank and or Lab Director/ Manager to discuss the impact of the indeterminate results on the donor evaluation and organ allocation.
- This discussion will be documented in the donor medical record.

Patients on Massive Transfusion Protocols-

- if a patient who is being assessed and/or managed as a donor is/or has been on a massive transfusion protocol, SHSC will immediate place further management of the case on "Hold" until the Administrator on call (AOC) and the Medical Director discuss the how to proceed and the impact of ABO results.
- This discussion will be documented in the donor record.

Monitoring Plan

- Monitor 100% of all cases of indeterminate results and massive transfusion protocol for documentation of discussion between AOC and Medical Director. Monitoring will include:
    - Donor ABO
    - Indeterminate Results and or Massive Transfusion Protocol with # of blood products
    - Documentation of:
        - Case hold
        - Discussion between AOC and Medical Director
        - Case Outcome

SHSC DQS Signature for closure: [redacted] Date: 01.16.2019

Grand Strand Health

Date: January 16, 2019

To: [redacted]
Director Quality Systems
We are Sharing Hope SC

Concerning patient [redacted] a patient at our facility beginning November 24, 2018, we have reviewed the handling and processing of blood bank specimens received on this patient beginning with her initial entrance to our Emergency Department as a trauma. All specimens were processed and handled according to policy and procedure, including initial and subsequent typing, and the emergency release of blood products.

Thank you,

[redacted]
Director of Laboratory Services
Grand Strand Health
[redacted]