February 22, 2019

[redacted]
Compliance Operation Analyst
United Network for Organ Sharing
[redacted]

Dear [redacted]

Thank you for your email requesting updated information regarding the ABO incompatibility case for Donor [redacted].

We continue to work diligently to address this very important issue and to continue to refine our processes to ensure that this event is not repeated. Since the MPSC Informal Interview, We Are Sharing Hope SC have the following updates:

1. We are requiring that all blood samples for ABO testing be evaluated for hemodilution and "qualified" using the process for serology testing. We performed a quality check of that process and the results can be seen in **Attachment 1**.

2. We have completed a second, and more formal, Case Review for this event.

    a. We reviewed the case in depth, including the potential impact of transfusions on ABO determination.
    b. We reviewed the Forward and Reverse Typing with clinical staff
    c. We discussed hemodilution and impact on ABO determination.
    d. We re-reviewed the ABO Determination in the Presence of Hemodilution Playbook and the companion worksheet. We reviewed the ABO Testing and Results Process Map with clinical staff.
        i. Note: We are working (with the MUSC Blood Bank Director) on developing a better organizational standard for Massive Transfusion Protocol Donors within SHSC. This definition must consider transfusions in the presence of a patient's Total Blood Volume (TBV) for a given patient (based on BMI) and must include a Pediatric Standard for Massive Transfusions.

The outline of this formal review can be seen in **Attachment 2.**

3. We finalized the ABO Determination and Results Process Map(s). They can be seen in **Attachment 3**.

4. We have scheduled a Lunch & Learn with the MUSC Blood Bank Director to review the ABO Determination Process and to further discuss the potential impact of transfusions and dilution on that process. The scheduled date is April 16th.

5. We have updated the standard clinical training to include the concept of ABO Determination and Forward and Reverse Typing and the potential impact of transfusions and hemodilution. This updated presentation can be seen in **Attachment 4.**

    a. Note: We are discussing whether to make ABO Determination a "Stand-Alone" presentation deck for new recovery staff.

6. We continue to update our policies to incorporate these new processes. Please see those update policies in **Attachment 5**.

7. We are performing a monthly review of the Hard Stop Process to ensure that staff adhere to this process as defined. The results of that quality review can be seen in **Attachment 6.**

Thank you for the opportunity to review our continued corrective actions with the committee. We appreciate the help and support you have given SHCS during this process and remain open to other thoughts or suggestions you may have.

[redacted]
Director Quality Systems

Attachment 1

ABO Qualification Review

Review each donor record to ensure ABO sample (s) have been qualified. Review the following pages and parameters:

1) Was the donor transfused any blood products (type and volume TX) , 2) Is there a pre-transfusion sample (date/time), 3) Pre-transfusion ABO , 4) was the hemodilution calculated completed and sample qualified, 5) Post- transfusion ABO / ABO #2 (date/time and type) , Post ABO #3 (date/time, type)

Review Month: February 2019

Donor ID	Donor Transfused	Pre-Transfusion Sample	Pre-Transfusion ABO	Hemodilution Calculation	Post- Transfusion ABO/ABO #2	Post- Transfusion ABO/ABO#3
[redacted]	No	02/7/19 19:40 VRL	O pos.	NA	02/7/19 19:50 VRL O pos.	NA
[redacted]	No	02/8/19 13:30 VRL	A(1) neg.	NA	02/8/19 13:40 VRL A(1) neg.	NA
[redacted]	No	02/8/19 23:35 VRL	O pos.	NA	02/8/19 23:30 VRL O pos.	NA
[redacted]	Yes 5 units PRBC 5 units FFP	No	NA	Yes Sample qualifies	02/10/19 18:30 VRL A (1) pos.	02/10/19 18:45 VRL A(1) pos.
[redacted]	No	02/10/19 9:50 Hospital	O pos.	NA	02/10/19 12:10 VRL	NA

[redacted]

					O pos.	
[redacted]	NA	02/12/19 19:07 Hospital	O pos.	NA	02/14/19 21:50 VRL O pos.	NA
[redacted]	Yes PRBC 300	No	NA	Yes Sample qualifies	02/14/2019 11:35 Hospital O pos.	02/14/19 15:30 VRL O pos.

Attachment 2

BDD [redacted] GRAND STRAND

PRE-AUTHORIZATION

[redacted] who was involved in a motorcycle accident on 11/24/18. [redacted] suffered a traumatic arrest in the field. ACLS measures continued into the ED as patient arrested multiple times. An obvious right arm deformity that was pulseless and cold was noted in the ED. Bilateral chest tubes were placed and pt was emergently taken to the OR. An ex lap was performed where a grade 1 liver laceration and hematoma were noted. A pericardial window was also completed in the OR. The right arm deformity was splinted. Pt was stabilized and transferred to the STICU.

True downtime total unknown due to multiple cardiac arrests in the ED and OR

UDS negative.
ETOH positive.

Head CT showed diffuse cerebral edema with transtentorial and tonsillar herniation, possible small SAH and IPH.

**Pt received a mass transfusion of various blood products (11 PRBC, 2 Platelets, 8 FFP, 1 Cryo) before type and cross match could be done by the hospital.

Areflexia noted upon admission 11/24/18 @ 2237
Referral called in 11/24/18 @ 2255

Pronounced BD 11/25/18 @ 1634 with clinical bedside exam, apnea, and CTA (per GS policy).

On the South Carolina registry, so there was consent for all organs, tissues, eyes, and research. 1st person disclosure signed by [redacted]

Horry County Coroner [redacted] gave permission for donation with special requests: admission blood and photos to be taken by SHSC.

POST AUTHORIZATION

Key Players:
NOK [redacted]
FSC [redacted]
CDCs [redacted]
CAT [redacted]
CDS [redacted]
[redacted] Pronouncing MD)
[redacted] TNVU abdominal transplant)
[redacted] (MUSC lung)
[redacted] (NCCM heart)

SEROLOGIES
+CMV, EBV IgG

Identified as increased risk due to a hemodiluted specimen was used for serology testing.

DONOR MANAGEMENT

Ht/Wt: 66"/129 lbs

ABO Indeterminant through VRL x 2 (hemodiluted specimen) 11/25/18 @ 1900 & 1905
Results page notes "FORWARD AND REVERSE BLOOD TYPES ARE DISCREPANT. FORWARD TYPE IS O NEGATIVE REVERSE IS A"

AOC was notified regarding the ABO results from VRL. It was decided to use a second ABO completed at hospital.
ABO typed as O through Grand Strand x 2 (hemodilution status unknown)
Hospital ABO #1- 11/24/18 @ 2309. Completed under pt's trauma name.
Hospital ABO #2- 11/25/18 @ 1950. 2nd ABO drawn when name changed from trauma to legal name (GS policy)
No mention of forward or reverse results on hospital reports.

Donor listed as O in DonorNet.

Terminal Labs

NA 148, Creatinine 0.72, Glucose 204

Echo WNL, EF 55-65% on vaso @ 0.04 and T4 @ 50 mcg

PO2 Challenges 473-529
Bronch showed bloody secretions in the RLL; Chest CT showed possible contusions or aspiration.

DMG BENCHMARKS

Coordinator at Milestone [redacted]

	At Referral	At OPO Start of Case	Initial Allocation	Prior to O.R.	Real Time DMGs	% Hourly Met	Mean	Min	Max
MAP 60-110	--	91	98	95	--	92	91.14	74	117
CVP 4-12	--	--	--	--	--	--	--	--	--
EF >=50%	--	--	65%	65%	65%	100	65%	65%	65%
ABG: pH 7.3-7.5	7.16	7.34	7.34	7.36	--	82	7.33	7.27	7.36
P:F Ratio >=300	308	240	528	529	--	100	498.83	435	529
PO2	246	340	528	529	--		455.3	174	529
FiO2	80	100	100	100	--		42	40	100
Sodium <=155	149	156	146	148	--	90	150	146	153
Glucose <=180	210	122	198	204	--	23	191.2	158	205
Urine Output >=0.5 cc/kg/hr	0.64 cc/kg/hr	--	1.42 cc/kg/hr	2.87 cc/kg/hr	--	95	0.48 cc/kg/hr	0.32 cc/kg/hr	1.27 cc/kg/hr
Urine Output (Total from previous 4 hours)	150	--	335	675	--		113.48	75	300
Low Dose Vasopressors 0-1	0	2	0	0	0	49	1	0	2
Total DMGs Met:	4	4	7	7	2	81	6	4	7

ORGAN PLACEMENT (discuss any allocation challenges)
Liver- TNVU (Vanderbilt University)
Kidneys- MUSC
Pancreas- WIUW (University of Wisconsin)
Lungs- MUSC
Heart- NCCM (Carolinas Medical Center)

TISSUE PLACEMENT Tissues and Corneas recovered

POST ORGAN RECOVERY DISCOVERY

CAT was notified by WIUW transplant coordinator stating ABO blood sent with the pancreas resulted as A. Pancreas transplant was aborted due to ABO incompatibility.

AOC notified of ABO discovery by WIUW

GS hospital blood bank called. They also got a discrepant result, but reran the ABO and resulted the pt as an O.

The heart and lung recipients began showing signs of acute rejection secondary to ABO incompatibility immediately after transplantation.

ABO run off blood sent with kidneys to MUSC also resulted as A.

ORGAN OUTCOME

Liver- TNVU. Recipient is [redacted] 45 year old [redacted] Liver had immediate function and recipient was listed as stable.

Kidneys- left to MUSC, right discarded.
Left kidney recipient is a 10 year old boy. He required dialysis after transplant, but listed as stable.

Heart- NCCM. Recipient had immediate post transplant complications, placed on ECMO and retransplanted. Stable after the 2nd transplant.

WHAT HAPPENED NEXT?

SHSC clinical and quality leadership teams began an immediately began an internal investigation.

The Hard Stop Process was developed. (*review with staff at end of presentation)*

The MPSC was also contact about the incident.

A Root Cause Analysis was conducted. It involved the blood bank staff from GS, along with the clinical staff involved.

Throughout the investigative process, it was internally determined that staff did not violate SHSC or UNOS policy. Though no policies were violated, SHSC realized our own policy needed to be better defined and a better process for ABO determination needed to be established.

SHSC leadership developed the playbook titled ABO Determination in the Presence of Hemodilution. (*review with staff at end of presentation)*

WHAT LEARNING OPPORTUNITIES WERE BE IDENTIFIED?

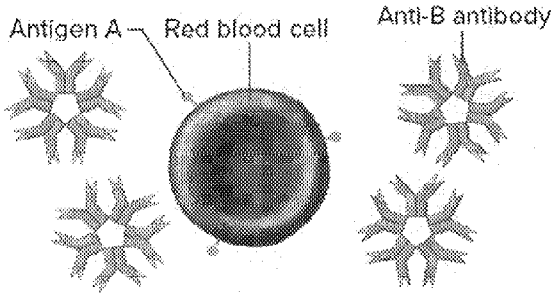
ABO TYPING

3 tests must be performed to determine blood type: ABO forward, ABO reverse, and D typing (Rh factor)

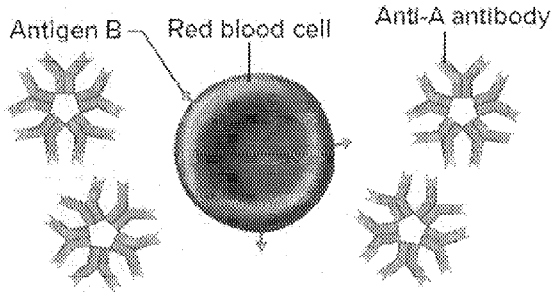
·Forward Typing- this test is used to detect the presence or absence of A and/or B antigens on ***red blood cells***. ABO group is *determined*.

·Reverse Typing- this test is used to detect ABO antibodies in ***blood plasma*** and is used to *confirm* the ABO forward typing.

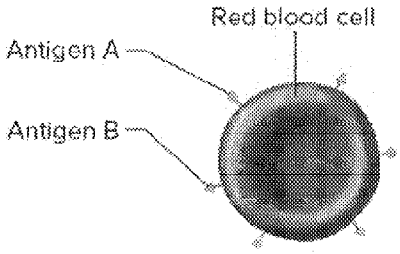
·D typing not relevant to transplantation.



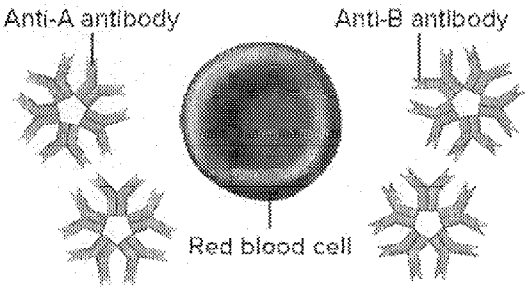
Type A blood



Type B blood



Type AB blood



Type O blood

Training Exercise:

Let's identify the ABO.

Forward (antigen)		Reverse (antibody)		Blood Type Interpretation
Antigen A	**Antigen B**	**Antibody A**	**Antibody B**	
none	none	+	+	
+	none	none	+	
none	+	+	none	
+	+	none	none	
none	none	+	none	

HEMODILUTION (hemo = blood) (dilution = decreased concentration)

In the most basic terms, it is the blood that is "watered down".

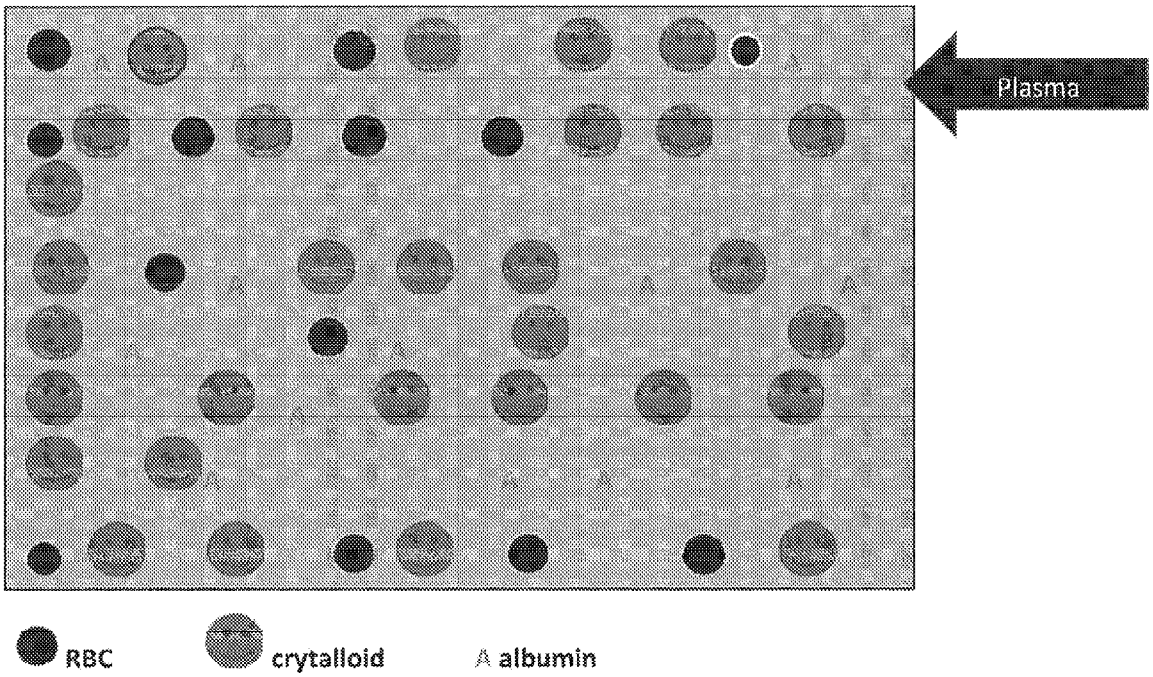
There are 2 ways to become hemodiluted:

1. Aggressive IV fluid resuscitation. The ratio of crystalloid and/or non-blood product colloid molecules is greater than the patient's own blood volume and circulating blood cells.

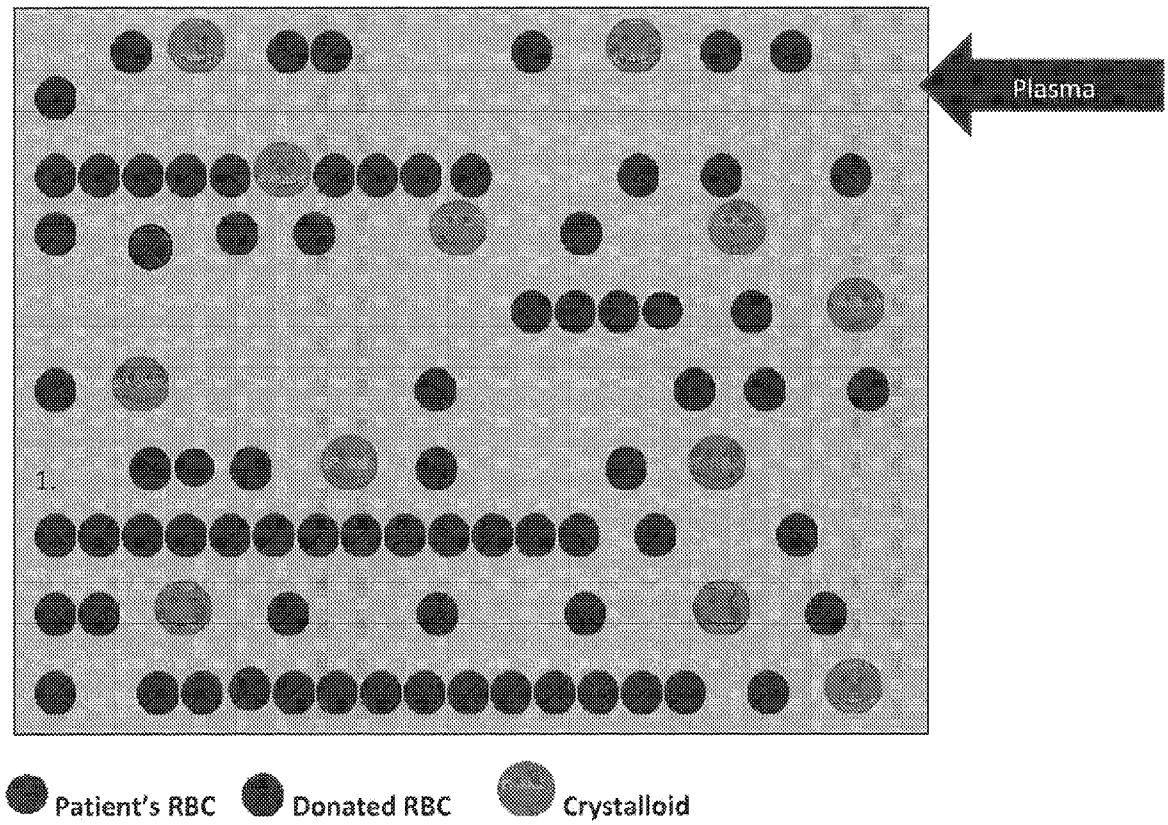
2. Massive blood product transfusion. The ratio of donated blood cells and/or plasma is greater than the patient's own blood volume and circulating blood cells.

Historically, a hemodiluted specimen was only a concern regarding the accuracy of serology testing. However, after learning more about ABO determination, can the staff understand how hemodilution can affect ABO typing? (*Discuss with audience*.)

1. Hemodilution w/ crytalloid and/or non-blood product colloid.



2. Hemodilution w/ blood products (mass transfusion).



SHSC Playbook

ABO Determination in the Presence of Hemodilution

The purpose of this document is to define the process for determining and communicating Donor ABO results in the presence of hemodilution.

The goal is to ensure recipient safety by adding an additional layer of evaluation and transplant center communication regarding an ABO determined using a hemodiluted sample.

Special attention must be given to donor patients where massive transfusion protocols were used as part of the pre-mortem care.

The process for ABO determination in the presence of transfusions is outlined below:

Massive Transfusion Protocol

SHSC will define a Massive Transfusion Protocol Donor (MTP-D) as meeting the following criteria:

- **Transfusion of >10 units of packed red blood cells (PRBCs) in 24 h**

When determining the transfusion volume, SHSC will evaluate transfusions prior to the draw date & time of the blood sample(s) used for donor ABO determination.

Donor ABO Determination

When possible, SHSC will use a pre-transfusion sample when determining the donor ABO if any transfusions received (independent of MTP or hemodilution status).

If a pre-transfusion specimen is not available, then SHSC should "qualify" any post-transfusion sample used for donor ABO determination. This qualification process is the same hemodilution calculation used for Donor Infectious Disease Testing.

If the sample used for Donor ABO determination is hemodiluted, then this information should be immediately communicated to the SHSC AOC and the Medical Director.

Donor ABO in the presence of Hemodilution (Guidance for the AOC and Medical Director)

If the Donor ABO has been determined using a hemodiluted blood sample, then SHSC action should include, but not be limited to the following:

1. Obtain an additional ABO using a sample that is not hemodiluted – i.e., is outside the hemodilution window. This ABO must be determined prior to the donor OR. *Hemodilution calculation will be performed on this sample.*
2. Review all available past medical records for the donor patient, to determine if there is another result that confirms the current ABO. *Hemodilution calculation not needed if unable to obtain IV infusion information for this ABO only.*
3. Consider using a more specific testing (if available) for ABO determination – i.e. molecular or similar – to determine ABO Type.
4. Consider registering the donor patient in DonorNet as an AB Blood Group; this will reduce the risk of an incompatible transplant.
5. Proceed with the donor ABO obtained from the hemodiluted sample and communicate to the accepting transplant centers.

Communication Protocol for a Hemodiluted Donor ABO

SHSC must document on the ABO results page – used to communicate the Donor ABO to transplant centers – that the sample was hemodiluted.

- The ABO result(s) page should have the words "Hemodiluted Sample" written on the page.

SHSC staff should also verbally communicate this information to accepting centers and document that conversation in the donor medical record (iTransplant).

Sharing Hope SC

Determining ABO in the Presence of Hemodilution

Worksheet

Step 1 – Determine if patient is a Massive Transfusion Protocol – Donor (MTP-D).

Did pt. receive > 10 units of PRBCs in last 24 hours (from date & time of ABO #1 or #2 blood draw)?

☐ **Yes (Notify AOC and Medical Director, then proceed to step 2)** ☐ No (Proceed to step 2)
If YES, pt. is MTP- D

Step 2 – If any transfusions received, locate a pre-transfusion sample for ABO determination.
Is there a pre-transfusion sample available? ☐ Yes ☐ No

If YES, obtain the sample and continue with ABO determination (Proceed to step 3)

If No, obtain the UNOS required sample(s) for ABO determination (Proceed to step 3)

Step 3 – Qualify blood sample for donor ABO determination – Use the hemodilution calculation in iTransplant. *Does the sample qualify?* ☐ Yes ☐ No

If YES, proceed with ABO determination. No further action needed.

If NO, sample is *hemodiluted*. Continue with ABO determination and proceed to step 4.

Step 4 – Notify SHSC Administrator On-Call (AOC) and Medical Director.

SHSC AOC and Medical Director Notified? ☐ Yes ☐ No

Select AOC and Medical Director recommendation:

☐ Obtain an additional ABO using a sample that is outside the hemodilution window. This ABO must be determined prior to the donor OR. *Hemodilution calculation will be performed on this sample.*

☐ Review available past medical records to locate another result that confirms the current ABO. *Hemodilution calculation not needed if unable to obtain infusion history for this ABO only.*

☐ Consider using a more specific test (if available) for ABO determination – i.e. molecular or similar – to determine ABO Type.

☐ Consider registering the donor patient in DonorNet as an AB Blood Group to ensure that there is no risk of an incompatible transplant.

☐ Proceed with the donor ABO obtain from the hemodiluted sample, while ensuring transparent communication to accepting transplant centers.

Step 5 – Document in Donor Medical Record and notify Accepting Transplant Centers.

Document "Hemodiluted Sample" on the ABO Results page(s) ☐ Yes ☐ No
Communicate to accepting transplant centers and document in donor EMR ☐ Yes ☐ No

Attachment 3

ABO Testing Process Map

1. **Pt is MTP – D?**
   Yes – [Notify AOC and Medical Director and proceed to step 2] No- [Continue with Algorithm to #2]

2. **Is there a Pre-Transfusion sample available?**
   Yes- [qualify the sample] No- [qualify the sample]

3. **Is any sample for ABO testing hemodiluted?**
   Yes – [Notify AOC and Medical Director] No- [Run sample & verify]

4. **Time to obtain a qualified sample?**
   Yes [Run Sample & verify x 3-HARD STOP] No- [Proceed to #5]

5. **Obtain an ABO from a different admission**
   Yes [use sample as ABO # 3 and verify] No- [Proceed to #6]

6. **Medical Director approves testing hemodiluted specimen**
   No – [HARD STOP]
   Yes – [Document "Hemodiluted Sample" on ABO Results page]
   Yes – [Consider registering the Donor as an AB]

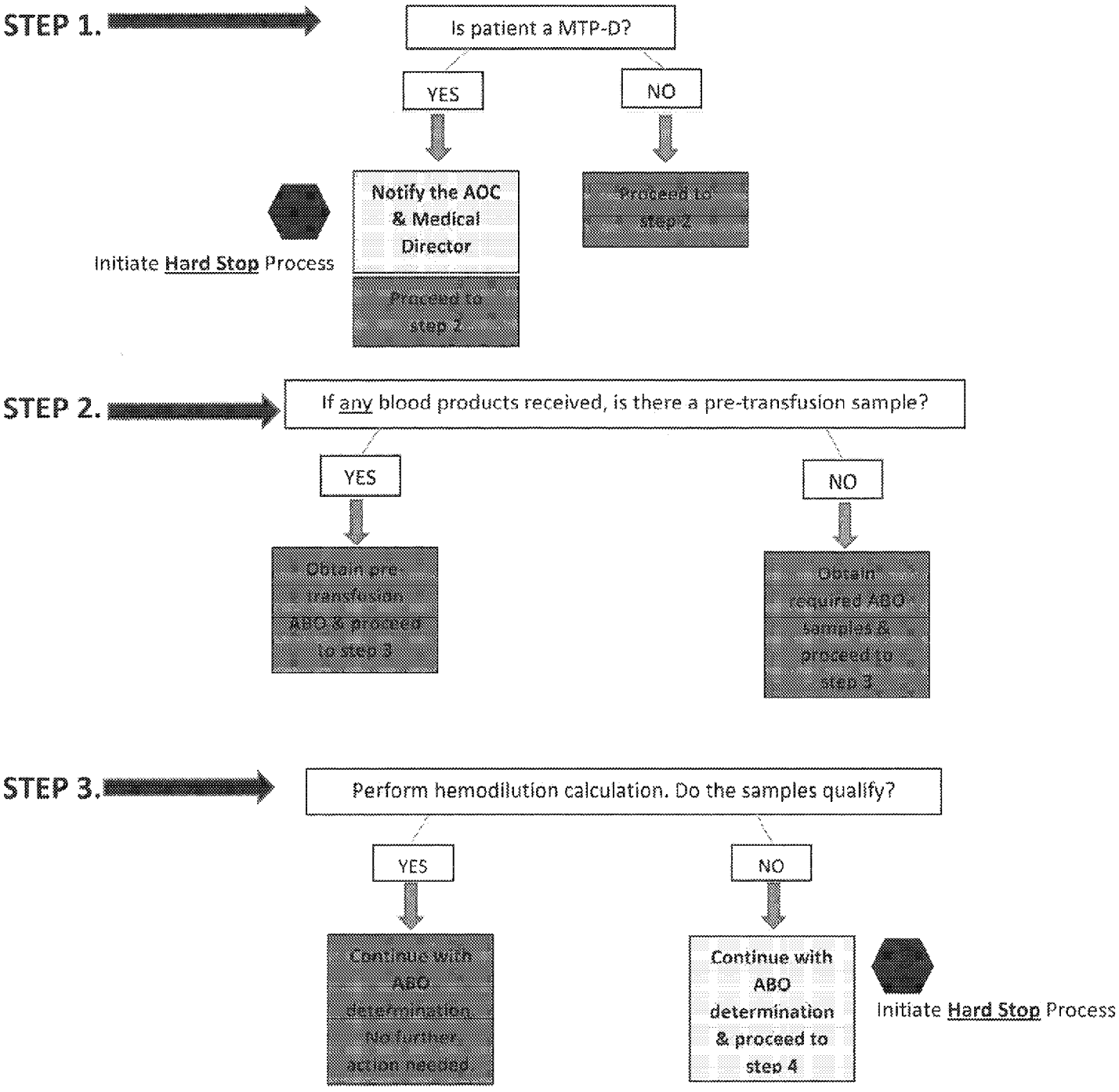
ABO Results Process Map

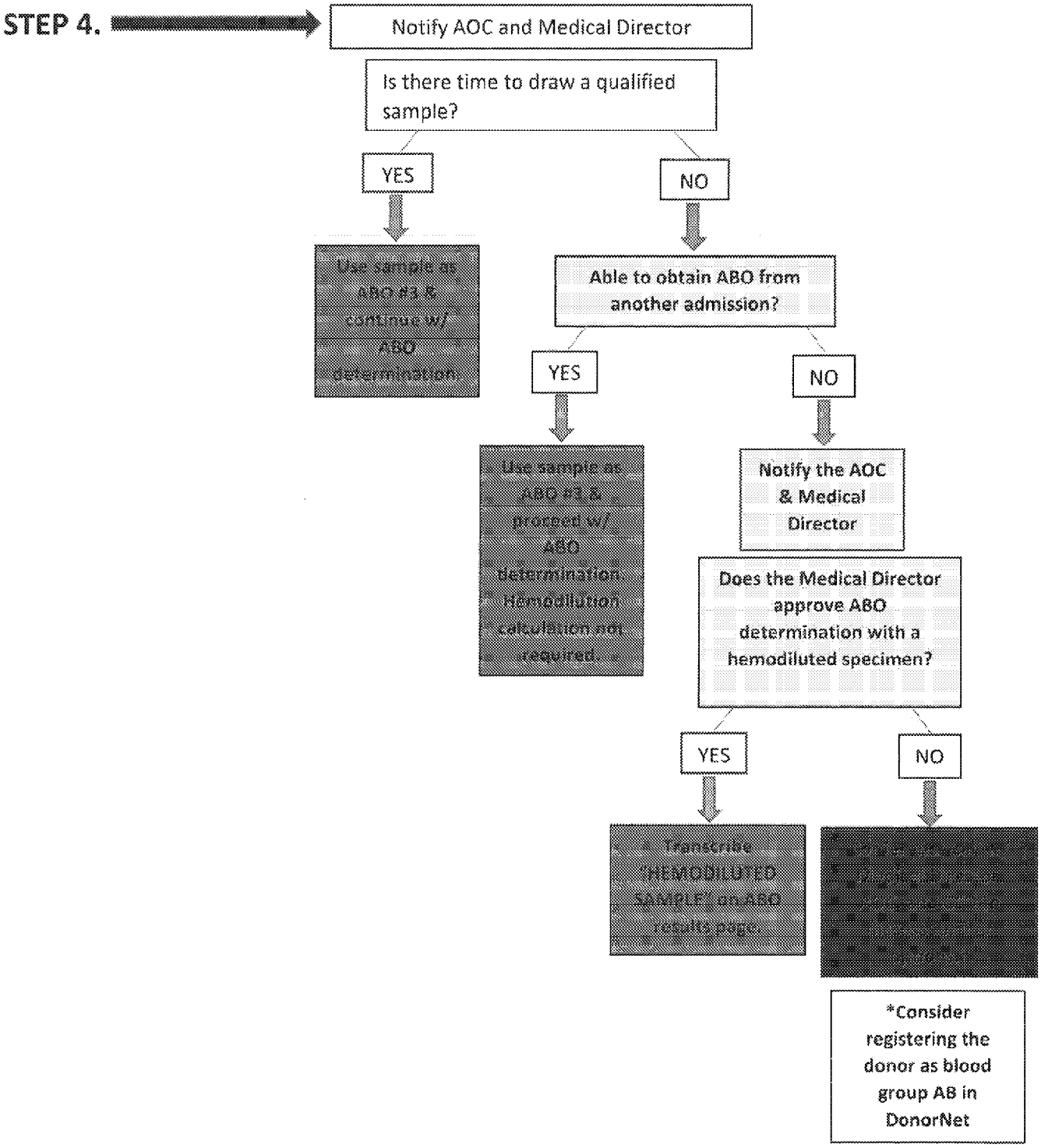
1. **Any ABO Results Indeterminate**
   No – [Proceed with Donation]
   Yes – [Notify AOC and Medical Director] [OPO MUST re-run another ABO x 2]

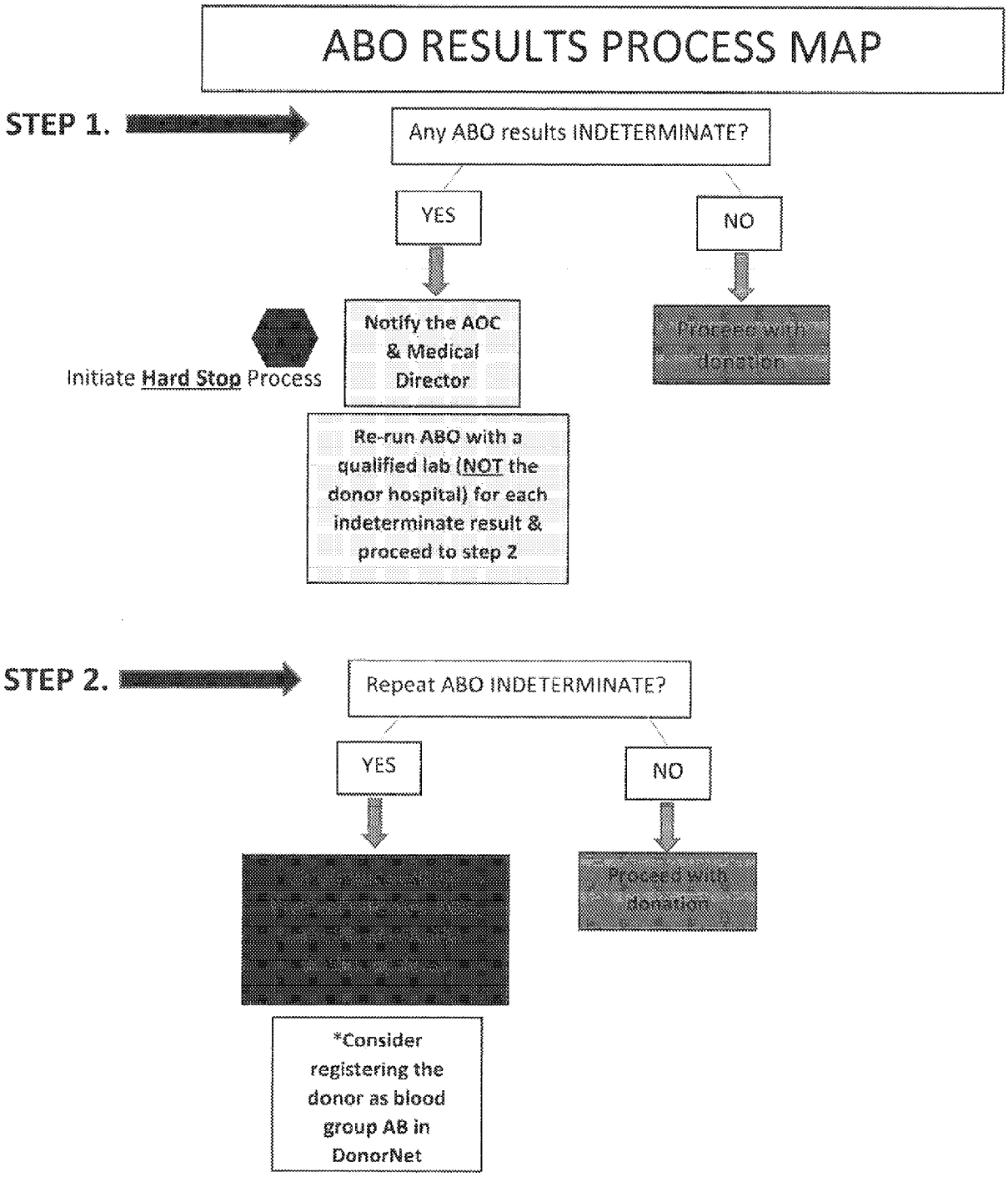
2. **Repeat ABO result is Indeterminate**
   No – [Proceed with Donation]
   Yes – [Notify AOC and Medical Director]

Special Note:
MTP-D + Hemodiluted ABO Testing Sample + Indeterminate Result = **Consider Registering Donor as AB**

ABO TESTING PROCESS MAP




STEP 4.
Notify AOC and Medical Director
Is there time to draw a qualified sample?
YES
NO
Use sample as ABO #1 & continue w/ ABO determination
Able to obtain ABO from another admission?
YES
NO
Use sample as ABO #1 & proceed w/ ABO determination. Hemodilution calculation not required.
Notify the AOC & Medical Director
Does the Medical Director approve ABO determination with a hemodiluted specimen?
YES
NO
Transcribe "HEMODILUTED SAMPLE" on ABO results pag
*Consider registering the donor as blood group AB in DonorNet


ABO RESULTS PROCESS MAP
STEP 1.
Any ABO results INDETERMINATE?
YES
NO
Initiate Hard Stop Process
Notify the AOC & Medical Director
Re-run ABO with a qualified lab (NOT the donor hospital) for each indeterminate result & proceed to step 2
STEP 2.
Repeat ABO INDETERMINATE?
YES
NO
Proceed with donation
*Consider registering the donor as blood group AB in DonorNet

Sharing Hope SC Donor ABO Disclosure

OPTN ID_____ SHSC Donor ID_____

This donor meets one or more criteria defined by Sharing Hope SC to disclose to the accepting transplant center(s) of the following ABO risk:

1. ☐ A hemodiluted specimen was used for donor ABO determination.

2. ☐ The donor ABOs were found to be ***INDETERMINATE*** by a qualifying lab. With the advisement of the SHSC Medical Director, the donor was registered in DonorNet with an AB blood type.

Reviewed with AOC _____

Reviewed with Medical Director _____

Clinician performing review _____

The recipient transplant center accepts sole responsibility for communicating all pertinent information regarding the transplant, the donor organ and risks to the intended recipient before transplantation.

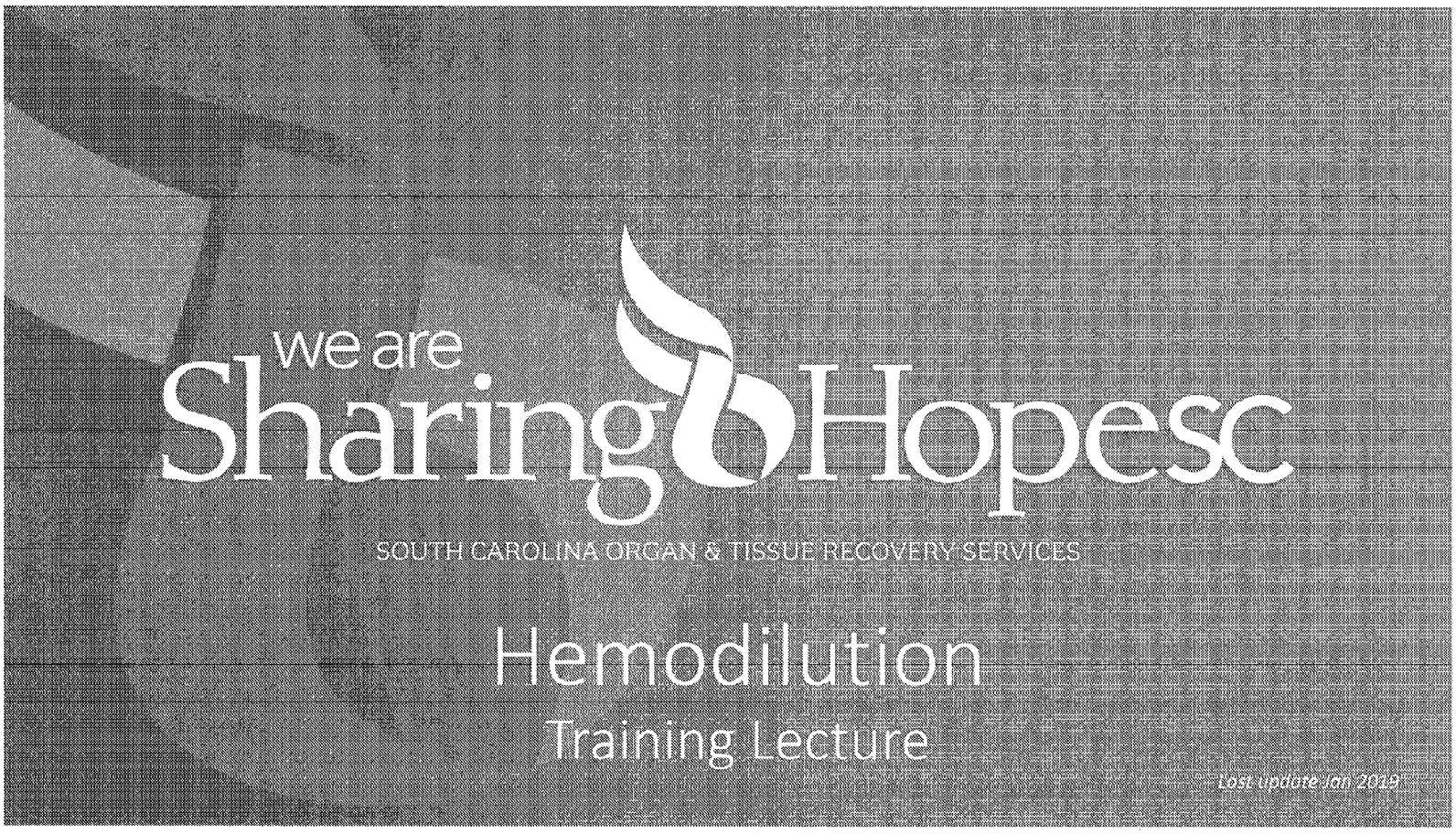
This form has been reviewed by the representative of the accepting transplant center. ALL signatures must be received from the accepting transplant center before the OR time can be set for organ recovery.

TX Center	TX Center Representative (print)	Signature	Title	Date	Time

SHSC Staff Signature_____ Date_____ Time_____

O 1.110-7 ABO Disclosure Form, Rev. 0
REV. TBD

Attachment 4


we are
SharingHopesc
SOUTH CAROLINA ORGAN & TISSUE RECOVERY SERVICES
Hemodilution
Training Lecture
Last update Jan 2019

Objectives

- Understand normal fluid volumes and distribution in the body and the state of hemodilution
- Understand how to determine hemodilution status and whether a donor sample "qualifies" for serologic testing
- Understand impact of hemodilution for organ and tissue donor suitability
- Recognize potential impacts of hemodilution on ABO and HLA typing

**Also Review Serology Testing Lecture*

Hemodilution

- Serologic infectious disease assays detect/measure components of our immune system (*e.g. antibodies*) or proteins (*antigens*) from an infecting organism which are dispersed throughout the blood in small concentrations.
- When there is an excess of fluid in the circulation, those assay targets (antibodies, proteins, etc.) may be too dispersed or diluted to be accurately detected by the test methodology.
- This is **hemodilution**. A donor who is hemodiluted may have falsely negative serology test results, putting recipients at risk of disease transmission.

Circulating blood volumes

- Based on a person's gender *(female/male)*, age *(adult/child)*, and weight *(kg)*, one may calculate her/his estimated circulating fluid volumes.
- There are several formulas available to do this; the hemodilution worksheet in iTransplant performs the calculation automatically with formulas that meet the requirements of organ and tissue regulating bodies.
- For each donor we need to estimate her/his:
  - **Total Blood Volume (TBV)**
  - **Total Plasma Volume (TPV)** *(the portion of the blood minus cells)*

Normal blood volumes and ratios

Blood Volume

- Amount of blood in the body is roughly equivalent to 7% of body weight.
  - Neonate 85-90 ml/kg
  - Infant 75-80 ml/kg
  - Children 70-75 ml/kg
  - Adult 65-70 ml/kg or ***"approximately 5L"***

Hematocrit

- Lab value that indicates the percentage of blood composed of red blood cells (RBCs)
  - Newborns: 55-68%
  - One week old: 47-65%
  - One month old: 37-49%
  - Three months old: 30-36%
  - One year old: 29-41%
  - Ten years old: 36-40%
  - Adults: 42-54% (M); 38-46% (F)

Alteration in blood volume

Some basic examples…

Event	Total Blood Volume	Hematocrit (Hct)	
Acute hemorrhage	↓	normal	*Losing equal amount of RBCs & plasma*
Severe burns	↓	↑	*Leaking plasma from the capillaries*
Crystalloid IV infusions	↑	↓ *(short term effect)*	*Temporarily increasing the plasma volume*
Blood transfusions - RBC	↑	↑	*Increasing RBC volume only*
Blood transfusions - FFP	↑	↓	*Increasing plasma volume only*

Types of IV transfusions/infusions

Donors may receive transfusions of blood products or infusions of crystalloid or colloid solutions. Some examples:

Blood Products	Crystalloids	Colloids
Whole blood	Normal Saline	Albumin (5%)
Packed Red Cells (PRBC)	Lactated Ringers	Albumin (25%)
Fresh Frozen Plasma (FFP)*	D5W	Hetastarch
Cryoprecipitate (Cryo)*		
Platelets (Plt)*		

**These are calculated under "colloids"*

These transfusions/infusions effect the circulating blood volume in different ways and their effects last for different periods of time.

Effects of transfusions/infusions

Blood cells, cellular components, or colloid solutions added to a patient's circulation exert an *osmotic effect*, tending to draw and hold fluid in the vasculature. This effect last for many hours.

- *We need to ascertain the total volume of blood products/colloids administered to the patient in the **48 hours preceding the sample draw** (organ) or **Time of Death (TOD)** (tissue).*

When crystalloid solutions are added, they briefly increase the patient's total circulating volume, but it is rapidly equalized, within about an hour.

- *We need to ascertain the total volume of crystalloids administered in the **1 hour preceding the sample draw** (organ) or **TOD** (tissue).*

Summary of transfusions/infusions

A. Total volume of blood transfused in the last 48 hrs:

RBC'S (packed cells)	(_____units x 350 mls)	= _____ mls	
Whole Blood	(_____ units x 500 mls)	= _____ mls	
Other Blood Products		= _____ mls	**Total of A: _____mls**

B. Total volume of colloids infused in the last 48 hrs:

FFP/ plasma	(_____ units x 275 mls)	= _____ mls	
Platelets	(_____ units x 50 mls)	= _____ mls	
Cryoprecipitate	(_____units x 10 mls)	= _____ mls	
Hespan/Hetastarch/Dextran (500 mls each)		= _____ mls	
Albumin 5%		= _____ mls	
Albumin 25%	(_____ mls x 1.4)	= _____ mls	
Other Colloids		= _____ mls	**Total of B: _____mls**

C. Total volume of crystalloids infused in last hour:

❑ NS ❑ RL/LR ❑ D_5W Other: _____ = _____ mls **Total of C: _____mls**

***Reminder*: The date/time used to establish the 48hr and 1hr periods is TOD for tissue and sample draw for organ.

Actual volumes should be listed, but acceptable volumes can be used if only units are documented in the record.
See L 17.000-4 Fluid, Medication, and Blood Product Volumes

Reminder: crystalloids may be given as a straight fluid administration AND in continuous IV medications

Qualification of the sample

Add up the infusion/transfusion volumes:

A = Total volume of blood in past 48 hours (mls)

B = Total volume of colloids in past 48 hours (mls)

C = Total volume of crystalloids in past hour (mls)

Evaluate:

#1 Is **B + C < TPV**?

#2 Is **A + B + C < TBV**?

If the answer to either #1 or #2 is NO,
the sample does NOT qualify for serology testing
(it is hemodiluted).

Researching transfusions & fluid administration

- ❑ Flowsheets – ED/EMS, OR, ICU, etc.
- ❑ Daily I/O records in patients EMR
- ❑ Transfusion records
- ❑ Speak directly to the blood bank
- ❑ Use standard/conservative estimates of volume administration
  e.g. - if EMS run sheet only documents that they "ran LR wide open," one could conservatively assume they administered 500-1000 ml LR.
- ❑ Check outside blood bank if patient transferred from another hospital!

****Rarely is it enough to just look at the flowsheets – do your due diligence!***

Suitable blood sample for serologic testing

The primary specimen sent for serology testing is obtained when initiating the organ or tissue case.

Tissue note:

- specimen must be collected no more than 7 days prior to or after donation
- if donor is ≤ 28 days, maternal hemodilution must also be calculated

Organ note:

- if donor was transfused, attempt to also obtain a pre-transfusion specimen
  - ***Reminder*** *- If a pre-transfusion sample is needed and the only one available is from admission, we must obtain permission from the Coroner/ME to use it, as that sample belongs to the Coroner when under their jurisdiction.*

Documentation

iTransplant (Organ Pre-Or Tab/Tissue Recovery Tab)

- Blood Products/Colloid Administration Summary
- Infusion/Transfusion Hemodilution Worksheet(s)
- Maternal Hemodilution Worksheet
- Serologies
- Call Notes (e.g.: document with whom you spoke in the blood bank)

Important Reminder: For organ donors, ALL blood products administered since admission need to be documented. Not only the past 48 hrs.

Remember: A separate hemodilution calculation must be done for each specimen being used for serology testing.

- Practice point: *On the blood products/colloid summary, the date/time entered should reflect when the transfusion volume was completed, not initiated.*

So...what if a specimen doesn't qualify?

Several options may be considered:

1. Investigate if there are other blood specimens retained in the lab that would qualify.
   Also check the available volume and type of specimen (serum/plasma)
2. Wait and obtain the specimen later, after enough time has passed for the patient to no longer be hemodiluted.
3. If the preceding options aren't available, for an **organ donor**, run the serologies on the available *non-qualified* sample and list the donor as *PHS Increased Risk*. Unfortunately this option isn't available for the tissue donor and they would be R/O.

Hemodilution and ABO Typing

- Historically, hemodilution calculations were used solely for determining specimen suitability for infectious disease testing.
- We are now aware that in situations where organ donors have undergone massive transfusions protocol, hemodilution may also impact validity of ABO typing.
- SHSC will define *massive transfusion* as a donor receiving > 10 units of packed red blood cells (PRBCs) within 24 hrs of sample draw.
  - In this circumstance, if unable to obtain pre-transfusion specimens for ABO typing, we must complete a Hemodilution Calculation (*in iTransplant*) for the ABO sample(s)

➥ *Please review* ***SHSC Playbook – ABO Determination in the Presence of Hemodilution***

ABO Typing

- 3 tests are performed by the blood bank to determine ABO type
  - ABO forward typing – *determines* the blood type by detecting the presence or absence of A and/or B **antigens** on the surface of the red blood cells
  - ABO reverse typing – *confirms* the typing by detecting A and/or B **antibodies** in blood plasma
  - D typing (for Rh factor) – not relevant to organ transplantation
- Patients who receive massive transfusions prior to undergoing typing have the potential for their natural ABO antigens and antibodies to be masked by the transfusions.
  - A red flag for this is if any of the blood bank results are reported as "indeterminate."

Policy/Procedures

Please thoroughly review the following:

- ❑ L 17.000 Blood Sample Suitability
- ❑ O 1.110 Specimens Drawn for Donor Evaluation
- ❑ *SHSC Playbook: ABO Determination in the Presence of Hemodilution*

Practice Scenarios

Complete the hemodilution practice cases.

OPTN Policy 2 – *for reference*

2.5 Hemodilution Assessment

OPOs must use qualified (non-hemodiluted) blood samples for deceased donor serological screening tests if available. If a qualified sample is not available for testing, a hemodiluted sample may be used for deceased donor screening tests.

If serological testing occurs on a hemodiluted blood sample, the host OPO must treat the deceased donor as presenting an increased risk for disease transmission as specified in the *U.S. Public Health Services (PHS) Guideline*.

Prior to screening, the host OPO must assess all potential deceased donor blood samples that were obtained for serological screening tests for hemodilution using a U.S. Food and Drug Administration (FDA) approved hemodilution calculation. The host OPO must document in the deceased donor medical record a complete history of all blood products and intravenous fluid transfusions the deceased donor received since admission to the donor hospital.

Additionally, the host OPO must report *all* of the following to the accepting transplant programs when a hemodiluted specimen is used in deceased donor screening tests:

1. Any screening results from the hemodiluted specimens.
2. The tests completed on the hemodiluted specimens.
3. The hemodilution calculation used for the hemodiluted specimens, if requested.

FDA Rule – *for reference*

Part 1271: Human Cells, Tissues, and Cellular and Tissue-Based Products

Subpart C: Donor Eligibility

§1271.80

(d) Ineligible donors. You must determine the following donors to be ineligible:

(1) A donor whose specimen tests reactive on a screening test for a communicable disease agent in accordance with §1271.85, except for a donor whose specimen tests reactive on a non-treponemal screening test for syphilis and negative on a specific treponemal confirmatory test;

(2) [1] A donor in whom plasma dilution sufficient to affect the results of communicable disease testing is suspected, unless:

(A) You test a specimen taken from the donor before transfusion or infusion and up to 7 days before recovery of cells or tissue; or

(B) You use an appropriate algorithm designed to evaluate volumes administered in the 48 hours before specimen collection, and the algorithm shows that plasma dilution sufficient to affect the results of communicable disease testing has not occurred.

(ii) Clinical situations in which you must suspect plasma dilution sufficient to affect the results of communicable disease testing include but are not limited to the following:

(A) Blood loss is known or suspected in a donor over 12 years of age, and the donor has received a transfusion or infusion of any of the following, alone or in combination:

(*1*) More than 2,000 milliliters (ml) of blood (e.g., whole blood, red blood cells) or colloids within 48 hours before death or specimen collection, whichever occurred earlier, or

(*2*) More than 2,000 mL of crystalloids within 1 hour before death or specimen collection, whichever occurred earlier.

(B) Regardless of the presence or absence of blood loss, the donor is 12 years of age or younger and has received a transfusion or infusion of any amount of any of the following, alone or in combination:

(*1*) Blood (e.g., whole blood, red blood cells) or colloids within 48 hours before death or specimen collection, whichever occurred earlier, or

(*2*) Crystalloids within 1 hour before death or specimen collection, whichever occurred earlier.

Questions & Discussion

The Presentation, Readings, and Resources for this training, may be accessed at any time at:

S:\Quality Systems Information\Training Module Library\Shared – Hemodilution

Attachment 5

	Standard Operating Procedure **Organ Recovery Services Manual**	Document Number	O 1.110
		Revision Number	16
	Specimens Drawn for Donor Evaluation	Revision Date	06/14/18
		Page 1 of 6	

1) Policy.

a) It is Sharing Hope SC policy to obtain specimens and perform testing on potential donors as part of the allocation process and to determine whether there are conditions which may influence donor acceptance.

b) The purpose of this document is to describe:

i) The procedure followed for obtaining specimens to be used for infectious disease testing, tissue typing, and ABO typing and subtyping at designated testing centers.

ii) When the organ donation process may proceed if there is a deviation or exception to the procedure.

iii) The procedure to follow if one or more infectious disease tests are positive.

iv) The procedure for providing the ABO type to DonorNet.

v) The procedure for verifying the ABO.

2) Definitions and/or Acronyms.

Term	Definition
ABO	A system used to identify specific blood types: A, B, O, or AB.
ABO Subtype	Serological testing process to identify ABO phenotypes. This process is performed on blood types A and AB. • Blood Group A Subtype Determination: A1-reactive group A is synonymous with A1-positive or A1, A1-nonreactive group A is synonymous with A1-negative, non-A1, or A2. • Blood Group AB Subtype Determination: A1-reactive group AB is synonymous with A1B or Blood Group AB, A1-positive, A-1 nonreactive group AB is synonymous with A2B or non-A1B or AB, A-1 negative. • **"Negative" does not refer to Rh type.**
ABO Testing Results	The printout of ABO typing results received from the ABO testing laboratory.
AOC	Administrator On Call.
CAT	Clinical Allocation Technician.
CDC	Clinical Donation Coordinator.
CDS	Clinical Donation Specialist.
DonorNet	The web-based donor and recipient database electronic utility used by the OPTN contractor.
EMR	Electronic Medical Record.
FSC	Family Support Counselor.
HLA	Human Leukocyte Antigen.
IAW	In Accordance With.
NAT	Nucleic Acid Test.
OPTN	Organ Procurement Transplant Network.
OPTN ID	A unique identification assigned by the OPTN when an organ donor is registered in DonorNet. (Also known as UNOS #, UNOS ID, or OPTN #.)
PPE	Personal Protective Equipment.
Pre red blood cell transfusion sample	Blood sample obtained prior to infusion of any red blood cells. No red blood cells, whole blood or packed red blood cells (PRBC), can be given for at least 120 days prior to the sample draw (the life span of a red blood cell) or it is not considered a true pre-transfusion sample.
QHP	Qualified Healthcare Professional: A person who is qualified to perform blood type reporting or verification requirements as defined in the OPO, transplant hospital, or recovery hospital written protocol. CATs, CDCs, AOCs, and CDSs are trained as Qualified Healthcare Professionals.
Source document	An original record of results or a photocopy or digital copy of the original record. Source documents can include laboratory printouts, DonorNet, Organ Verification form printouts from DonorNet, EMR documentation, and hospital medical record.
2-person Verification	A verification conducted by two separate individuals confirming the accuracy of information (from a source document) and/or completeness of a document or process.

3) Scope and Responsibilities.

a) This document applies to the FSC, CDC, CAT, CDS, and AOC/Designee of the Organ Recovery Services.

Position	Responsibility
FSC CDC CDS	• Create labels for specimens drawn for donor evaluation. • Ensure that sufficient specimens are obtained from the potential donor so that appropriate testing can be performed. • Notify the AOC/Designee when adequate pre-transfusion samples are not obtained and follow the AOC/Designee's instructions.
CAT/Desginee	Access DonorNet and document the ABO for each potential donor.
AOC/Designee	Verify the ABO in DonorNet for each potential donor.

4) Materials and/or Equipment.

a) Lab specimen transport box.
b) HLA specimen transport box.
c) Red, purple, and yellow top blood tubes provided in the specimen transport boxes.
d) Applicable testing facility's requisition form.
e) PPE IAW ***S 1.000-4 Personal Protective Equipment (PPE) Requirement – Organ.***
f) Access to DonorNet.
g) Dymo Label Writer or TransNet labeling system.

5) Procedure.

a) Obtaining and Labeling Blood Samples.
   i) Blood samples are obtained as soon as possible after brain death declaration has occurred (or death is imminent) and authorization has been obtained.
   ii) Labels for blood samples will be generated by an electronic labeling system that auto-populates previously verified information. If the electronic labeling system is unavailable, contact the AOC/Designee.

Responsible Person	Step	Action
FSC CDC CDS	1	Draw the appropriate blood samples. Document the lot # and expiration date of the blood tubes in the EMR on *Organ Pre-Or> Supply List – Organ.* • In events when donor size, such as a pediatric donor, or hemodynamic stability are of concern, the AOC/Designee and the designated testing center will be involved to determine the appropriate amount of samples to be collected and a strategy will be discussed to obtain all appropriate samples. • Mother's blood will be drawn on all pediatric donors under 28 days old IAW ***L 17.000 Blood Sample Suitability.*** Mother's blood will also be drawn on pediatric donors ≤18 months of age and donors <12 years old who have been breastfed in the past 12 months if the mother's Donor Risk Assessment Interview (DRAI) indicates she is identified as increased risk per Public Health Services (PHS) guidelines.
FSC CDC CDS	2	Determine if the samples are pre red blood cell transfusion specimens by comparing the sample draw times with times of any red blood cell administration during the previous 120 days. History of red blood cell transfusions should be determined by reviewing the patient's hospital medical record, blood bank record, and DRAI.

FSC CDC CDS or Designee	3	At a minimum, blood samples are labeled with the following information: • OPTN ID if known. • ABO if known. • Donor date of birth. • Donor ID. (or Case ID) • Date and time of collection. • Specimen type (blood, nodes, etc.). o If blood is drawn from the donor's mother, label as mother's blood. • Draw site location. • Initials of the labeler or donor.
CDC CDS or Designee	4	Identify if the donor is considered a MTP-D (Massive Transfusion Protocol Donor). This is defined as the **Transfusion of >10 units of packed red blood cells (PRBCs) in 24 hours.** • If MTP-D is identified, then the Hard Stop Process will be initiated and the appropriate steps will be taken IAW Playbook: ABO Determination in the Presence of Hemodilution.
CDC CDS	5	Perform a hemodilution calculation on the samples sent for infectious disease testing IAW ***L 17.000 Blood Sample Suitability***. • If the sample is hemodiluted, efforts will be made to obtain a non-hemodiluted sample. • If a qualified sample is not available, a hemodiluted sample will be used for testing. The donor will be considered as having increased risk for disease transmission and be handled IAW ***O 3.033 Communication of Increased Risk Factors***.
CDC CDS	6	Perform a hemodilution calculation on the samples sent for ABO Determination. • If the sample is hemodiluted, then the Hard Stop Process will be initiated while efforts are made to obtain a qualified sample. If a qualified sample is not available, then the appropriate steps will be taken IAW Playbook: ABO Determination in the Presence of Hemodilution.

b) Packaging and Transport of Specimens.

Responsible Person	Step	Action
FSC CDC CDS	1	Complete an applicable requisition form for each draw time of samples being sent. • ***O 1.100-1 HLA Deceased Donor Requisition.*** • Serology Lab Requisition. • ABO Lab Requisition. • NAT Lab Requisition.
FSC CDC CDS	2	Package the specimens in the appropriate transport box for shipment IAW the shipping instructions located inside the transport box. • Place the applicable completed requisition form(s) inside the transport box. • Complete all labels affixed to the box, as applicable.
FSC CDC CDS	3	All specimens will be transported in a timely manner. • Serology, NAT, and ABO specimens will be transported from the donor hospital to the lab for testing.

		• HLA specimens will be transported from the donor hospital to the HLA lab.
FSC CDC CDS	4	Local couriers may be used to transport specimens. • Complete any necessary paperwork (e.g. Bill of Lading, courier billing form, **F 5.000-1 Donor Services Provider Reimbursement Order**, etc.) and document the Donor ID and the type of specimen on the applicable form. If a local courier is unavailable, MNX will be used for courier services. • Call the Customer Center to arrange transportation with MNX. • Document the following information on ***F 5.000-1 Donor Services Provider Reimbursement Order***: o First and last name of the courier. o Date and time of pick-up. o Job number. o Intended destination. See ***O 4.140-8 MNX Resources*** for further details about MNX courier services.

c) SHSC Required Infectious Disease Tests for Organ Donors.

i) Serologies to include, but not limited to:

Test	What it screens for	Possible lab result name
Anti-HIV I/II	HIV-1 and HIV-2 antibodies	HIV 1&2 PLUS O Ab
HTLV I/II	Human T-lymphotropic virus	HTLV I/II Ab
HBsAg	Hepatitis B antigens found on surface of virus	Hepatitis Bs Ag
Anti-HBc	Hepatitis B antibodies to core antigen of the virus	Hepatitis Bc Ab
Anti-HCV	Hepatitis C antibodies	Hepatitis C Ab
HIV-1 NAT (HIV RNA) HepC NAT (HepC RNA) HepB NAT (HepB RNA)	Hepatitis C RNA (genetic material of virus)	HIV-1/HCV/HBV NAT (Ultrio)
Anti-CMV	Cytomegalovirus antibodies	CMV Ab
Anti-EBV	Epstein-Barr Virus antibodies	EB VCA IgG
VDRL or RPR	Syphilis non-specific antibodies	RPR (Non-treponemal syphilis)
Toxoplasma IgG	Antibodies to the parasite Toxoplasma gondii	Toxoplasma IgG
HBs Ab*	Hepatitis B antibody	Hepatitis Bs Ab
**HBsAb will be run if the Anti-HBcAb is positive. HBcAB is run if HBcAb IgM is positive*		

ii) An HIV-1 WB will be run at the discretion of the AOC/Designee, if the Anti-HIV I/II is positive.

iii) Additional tests may be performed as requested by the transplant center.

iv) Donor testing for infectious disease will be performed in a CLIA-certified laboratory utilizing FDA licensed, approved or cleared serological screening. In the event that screening tests cannot be performed or are unavailable, FDA approved diagnostic tests will be utilized. Diagnostic testing cannot be used to perform Anti-HIV testing.

v) See ***L 17.000 Blood Sample Suitability*** for a list of approved tests performed by each contracted laboratory.

vi) SHSC utilizes a 2-person verification process to verify the documentation of serology results.

Responsible Person	Step	Action
CDC CAT/Designee	1	The testing facility will forward the results to the CDC or CAT.
CDC CDS AOC/Designee	2	Review the printed results and document the results in the EMR on *Organ Pre-OR> Serologies.*

CAT/Designee CDS CDC AOC/Designee	3	Verify the serology results entered into the EMR against the hard copy report. Document this verification in the EMR and upload the results to DonorNet and the EMR.

d) Positive Infectious Disease Testing Results.

i) Organs are allocated IAW Organ Procurement Transplant Network (OPTN) policy.

Responsible Person	Step	Action
CDC CAT/Designee	1	Notify the AOC/Designee of any reactive test results.
CAT/Designee	2	Notify the SHSC Communication Center of any positive results if a mutual organ/tissue donor.
SHSC Policy	3	The appropriate staff member at the donor hospital will be informed of all positive HIV results for the purpose of following their internal hospital policy for these results.
CAT/Designee	4	Notify any transplant and/or research organizations involved with the donor, as needed.
Quality Systems	5	All reportable positive serology results are reported IAW ***Q 27.000 Sharing and Reporting Positive Serology Reports***.

e) ABO Determination.

Responsible Person	Step	Action
CDC CDS	1	All donors' blood types will be accurately determined by testing two separate donor blood samples from two separate draw times. When a donor is determined to be blood type A or AB, subtype testing will also be performed on two donor blood samples from two separate draw times if both samples are pre red blood cell transfusion samples.
CDC CDS	2	Sub-typing will only be used for the purposes of organ allocation if both sub types are pre red blood cell transfusion specimens.
CDC CDS	3	If any ABO results as **INDETERMINATE,** then the "HARD STOP" Process will be initiated and the appropriate steps will be taken IAW Playbook: ABO Determination in the Presence of Hemodilution.

f) ABO Verifications.

i) Sharing Hope SC utilizes a 2-person verification process to verify all ABO types and subtypes.

Responsible Person	Step	Action
CDC CDS	1	Upon receiving both of the ABO and subtyping test results, compare the results (typing and subtyping) and the donor name or OPTN ID to ensure they are the same. • If discrepancies are found, then the Hard Stop Process will be initiated and the appropriate steps will be taken IAW Playbook: ABO Determination in the Presence of Hemodilution. • Send all verified ABO and subtype testing results to the CAT.
CAT/Designee	2	Complete ***O 1.110-5 CAT ABO Verification*** after receiving all ABO testing results and confirming if samples are pre red blood cell transfusion samples. If ABO subtypes are not used for allocation, the reason will be documented on ***O 1.110-5 CAT ABO Verification***. • Document the ABO and subtype in the EMR on *Organ Pre-OR> Donor Information*. • Enter the ABO into DonorNet as instructed by ***O 1.110-5 CAT ABO Verification***. • Document the verification in the EMR on *Referral> Organ Donor Task Checklist*.

AOC/Designee	3	After verifying the ABOs, subtype results, and ***O 1.110-5 CAT ABO Verification***, access DonorNet and select the donor by name and OPTN ID. • Enter the ABO and subtype, if applicable. Only enter ABO A and AB subtypes into DonorNet if all of the following conditions are met: there are two separate samples from different draw times, both samples are pre red blood cell transfusion samples, and both samples are subtyped. o If any of these conditions are not met, then only the ABO blood group A or AB should be entered for organ allocation. • This verification step is documented within DonorNet.
Qualified Healthcare Professional Physician/Designee	4	A verification of the donor ID, donor blood type, and subtype (if used for allocation) will be performed prior to incision IAW ***O 4.020 Organ Recovery***.

6) Attachments.

a) O 1.110-4 HLA Deceased Donor Requisition.
b) O 1.110-5 CAT ABO Verification.
c) O 1.110-6 Blood Draw for Deceased Donors.
d) Hard Stop Process Playbook
e) ABO in the Presence of Hemodilution Playbook

7) Referenced and Related Procedures.

a) L 17.000 Blood Sample Suitability.
b) O 3.031 Organ Placement.
c) O 3.033 Communication of Increased Risk Factors.
d) O 4.020 Organ Recovery.
e) Q 27.000 Sharing and Reporting Positive Serology Reports.
f) S 1.000 General OSHA Information.
g) S 3.000 Bloodborne Pathogen Policy.
h) T 4.170 Obtaining Blood Samples for Testing.
i) T 4.171 Packaging and Transport of Blood for Serology Testing.

8) Standards and Regulations.

a) Association of Organ Procurement Organizations (AOPO) Standards: CL 4A.4; CL 4B.3; CL 4D; CL 4D.2; CL 4D.2.1; CL 4D.4; CL 6.6.1; CL 9.1.2.
b) Centers for Medicare and Medicaid Services (CMS) 42 Code of Federal Regulations (CFR) Chapter IV §: 486.344(c); 486.344(d)(2); 486.344(e); 486.346(a).
c) Organ Procurement Transplant Network (OPTN) Policies: 2.5; 2.6; 2.7; 2.9; 2.15.B(3); Table 4-1.

Attachment 6

ABO Typing Hard Stop Monitoring

Instruction: Review each donor record for determination if donor meets criteria for massive transfusion (transfused greater than /equal to 10 units of RBC= hemodilution) or reported indeterminate ABO typing results. For donor that meet the criteria document each of the parameters below. Review sample size- 100%.

Review Month: ____December 2018- updated 02.24.19

Parameter	Donor ID AFLR053	Donor ID AFL5371	Donor ID	Donor ID	Donor ID
Date/Time of Admission	12/06/2018 time not documented	12/30/18 00:04			
Pre-Transfusion Sample available	12/6/18 ~ 7:55	Not documented			
Pre-Transfusion Blood Type Results (if available)	A pos.	Not documented			
# and Type of Blood Products Given	RBC- 17 units- O pos. FFP- 8 units – A Pos. Plts- 2 units- A neg.	RBC- 18 units O-Pos. FFP- 8 units – 4units A-Pos 4units- A-neg. Plts- 2 units- O-Pos.			
Date and Time /Results of 1st ABO	12/18/18 18:50- VRL lab	12/31/18 17:40 VRL Lab			

	A-Pos.	O-Pos.			
Date and Time/Results of 2nd ABO	12/19/18 18:20- VRL Lab A-Pos.	12/31/18 17:50 VRL Lab O-Pos.			
Date and Time /Results of 3rd ABO (if applicable)	NA	01/01/19 11:15 Hospital 0-Pos.			
ABO Typing documented as Post- Transfusion	Yes	Yes			
Date and Time of Indeterminate ABO results (identify lab source)	NA	NA			
Date and Time Hard Stop Initiated – CDC/AOC	12/18/18 23:29 CDC/AOC	12/31/19 15:19			
Medical Director Directive documented	12/19/18 17:51 MD directive- run as "A" donor	AOC documented determination to "run"			
Final ABO determination (allocation)	A Pos.	O-Pos.			
Comments	NA	AOC note did not clearly document Medical Director directive- DQS verified MD directive during record review.			