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SC Court of Appeals

THE STATE OF SOUTH CAROLINA
In The Court of Appeals

Appeal from Charleston County
Court of Common Pleas
The Honorable Debra R. McCaslin, Circuit Court Judge

Appellate Case No: 2021-000487

Trial Court Case No: 2020-CP-10-02902

Michelle Cha Holliman, individually, and as Personal Representative of the Estate of Allen B. Holliman,

Respondent,

v.

We Are Sharing Hope SC, Medical University of South Carolina, United Network for Organ Sharing, Jacqueline Honig, M.D., and Darla Welker,

Defendants,

Of which We Are Sharing Hope SC and United Network for Organ Sharing are the

Appellants.

RESPONDENT'S MOTION TO DISMISS APPEAL FOR MOOTNESS

The Respondent moves this Honorable Court to dismiss the appeal in the above referenced matter because many, if not all, of the documents at issue in the appeal have now been publicly released by the United States Senate. The case underlying this appeal is a matter of significant state and national interest. *See e.g.*, *Exhibit A* (Post & Courier article); *Exhibit B* (Washington Post article). The Appellants claim that they are entitled to take an immediate appeal of a Circuit Court Order directing them to produce documents that are crucial to this litigation. Rather than release those documents as ordered by the Circuit Court, the Appellants represent to this Court that they

are entitled to take an immediate appeal and to extend a "peer review privilege" that clearly does not apply to them.

This past week, many, if not all, of the documents central to this appeal were made public by the United States Senate Finance Committee which has posted them on its website. *See* *https://www.finance.senate.gov/hearings/a-system-in-need-of-repair-addressing-organizational-failures-of-the-uss-organ-procurement-and-transplantation-network* A sample of those documents are attached as Exhibit C for the Court's review. Interestingly, the Senate Finance Committee chastised the Appellant UNOS for doing precisely what it has done in this litigation -- asserting non-existent privileges to try to avoid producing documents: "Throughout the course of the Committee's investigation, UNOS sought to withhold documents relevant to the Committee's inquiry. . . . even after the Committee issued a subpoena to UNOS on February 3, 2021, UNOS continued to withhold relevant information from the Committee without asserting a recognized constitutional, federal statutory, or federal common-law privilege applicable in response to a valid federal subpoena." Committee Report at 17. Appendix B to the Committee's Report discusses the instant case in detail at pages 23-27 and attaches to the Report 325 pages of documents that Respondent believes to be many of the documents at issue in this appeal.[1]

These documents have also now been publicly reported in *The Washington Post. See* https://www.washingtonpost.com/health/2022/08/03/transplant-deaths-mistakes-senate-finance/ reporting on the case at hand that "The South Carolina case involved a donor who died after a motorcycle accident and had received massive blood transfusions. The transplant of her organs was coordinated by We Are Sharing Hope SC, the OPO responsible for most of South

[1] Respondent, of course, has not seen the documents that Appellants have refused to produce despite a Court Order that they do so.

Carolina, records show. A first test failed to pinpoint a blood type, showing signs of both type O and type A. A second test was also indeterminate. But a third test showed signs of type O. A later investigation by UNOS and the OPO found that the indeterminate results were not fully communicated to surgeons who accepted the donor's organs. The mistake was not discovered until about nine hours after the donor's organs had been removed, documents show. A surgeon at another hospital who had received the donor's pancreas noted the organ was labeled type O, but a blood test run there showed type A. The surgeon was concerned and canceled the pancreas transplant. But it was too late for the others. Four had already been transplanted." (emphasis added).

It is the Respondent's position that the appellants are not entitled to take an interlocutory appeal of a circuit court's discovery order, that South Carolina's peer review statute does not apply to them since they are not a hospital, and that the issue on appeal is now moot since many, if not all, of the documents at issue have been released publicly.

Respectfully submitted,

/John C. Moylan, III

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August 17, 2022

EXHIBIT A

https://www.postandcourier.com/health/he-died-when-he-got-the-wrong-lungs-it-wasnt-the-only-organ-error-in/article_c6a6e386-e704-11ea-91ce-2783df6c6f2d.html

He died when he got the wrong lungs. It wasn't the only organ error in SC that day.

BY MARY KATHERINE WILDEMAN MKWILDEMAN@POSTANDCOURIER.COM

SEP 11, 2020



Allen Holliman died in 2018 after a lung transplant at MUSC. His wife, Michelle, has filed a lawsuit related to his death. The couple lived in Aiken, where Allen was a real estate agent. Provided

PROVIDED/MICHELLE HOLLIMAN

After the blood type of a South Carolina organ donor was incorrectly identified, a man in Charleston who'd received the donor's lungs died and another patient in Tennessee who received the liver was gravely injured. Both of their bodies rejected the donor's organs on the same day in late 2018.

Experts say the errors should never have happened.

A Charleston nonprofit called We Are Sharing Hope SC recovered and shipped the donor's lungs to the Medical University of South Carolina and sent the liver to a hospital in Nashville. One of 57 organ procurement organizations like it in the country, We Are Sharing Hope SC is the only one operating in most of this state.

Few things in medicine are considered as precious as a solid organ donation, especially from someone who has died. To mix up the match between the donor's and patient's blood type is rare, experts say.

"That, in principle, should never happen," said Dr. Bryan Whitson, a transplant surgeon and researcher at the Ohio State University Wexner Medical Center.

Allen Holliman had staked his hopes of surviving his incurable disease on the lung transplant he received in Charleston on Nov. 28, 2018. Though there is a policy in place making sure it's notified of the worst medical mistakes, no one told the S.C. Department of Health and Environmental Control about the circumstances of Holliman's death.

The case is an echo of another botched transplant at Duke University in 2003. That teenager's death captured national attention and brought about a reckoning for the organ-matching process.



Allen Holliman (right) died at MUSC in 2018 after receiving a lung transplant of a blood type that didn't match his. His wife, Michelle (left), filed a lawsuit against several entities for his death. The Hollimans enjoyed traveling and moved to South Carolina in 2014 to find a slower pace. Provided

The mistake that killed Holliman in Charleston has generated little attention, despite the similarity in circumstances. Two regulatory bodies said they would review the case when The Post and Courier started asking questions. The public wouldn't know about Holliman's death at all if not for his wife's lawsuit against the state's top academic medical center and We Are Sharing Hope SC.

A tough diagnosis

Allen and Michelle Holliman moved to Aiken in 2014 to find a slower pace of life down South, but that was hard for a gregarious man who thrived on interactions with others. The former owner of a limousine service, he became a real estate agent when they moved from Connecticut.

Allen's diagnosis of pulmonary fibrosis came as a surprise. The condition has no known cause or cure and makes lung tissue thicken and stiffen. It becomes harder — and eventually impossible — to breathe over time.

Before long, Allen was wearing a breathing tube and carrying an oxygen tank, and the couple was making regular trips to MUSC in Charleston.

Allen refused to be deterred by the diagnosis.

"He had a lot of hope," Michelle said.

His doctors didn't expect him to live without a transplant, **Allen wrote in an online fundraiser he started to gather the money he needed for a new set of lungs**. The total cost of the transplant could be at least $280,000, **according to one study**. Although his insurance would cover the procedure, Allen was asking for $50,000 to help cover all the extra costs associated with recovery, including rent in Charleston and his medications.

Michelle remembers all the conversations about the risks and Allen's chances of survival after transplant, which they understood would never be perfect.

"I've been a fighter for my whole life. I've worked hard for my family, my community, and my faith. I want to keep fighting," Allen wrote on his GoFundMe page. "My two daughters, my wife, my brother and his family, and my friends are all supportive. With them, and God at my side, I feel that I have a good chance to live a longer life."

Allen didn't wake up for the phone call that came early one morning a few days after Thanksgiving in 2018. But Michelle heard it, and rushed to pick up the phone. It was the news they had been waiting for, and sooner than they hoped: A pair of lungs was available.

They rushed out the door to drive three hours to MUSC.

After arriving at the hospital, Allen posted on Facebook that the surgery was supposed to begin at 8 a.m. Friends shared their prayers for a safe procedure. As the medical team rolled him into the operating room, Allen flashed a smile and a thumbs-up to his wife.

“He probably was nervous, actually,” Michelle said. “But not to me.”

Fatal error

Only about a month after Allen Holliman won a spot on the transplant waiting list, someone was dying at Grand Strand Medical Center in Myrtle Beach. According to Michelle Holliman’s lawsuit, the medical team there gave the patient a massive blood transfusion in a bid to save his or her life.

Who this person was and why they died is confidential because of patient privacy rules.



HEALTH

MUSC’s lung transplant program scores poorly. The hospital says it’s getting better.

BY MARY KATHERINE WILDEMAN MKWILDEMAN@POSTANDCOURIER.COM

We Are Sharing Hope SC, the organ network that operates in 44 of South Carolina’s 46 counties, is the organization that picks up the phone when someone progresses to brain death at one of the state’s hospitals.

The nonprofit ordered a lab to run tests on the donor’s blood. But because of the blood transfusion the patient had received, the results of the blood-typing test were inconclusive, according to court records.

Here, the process began to break down.

We Are Sharing Hope SC registered the donor’s organs with the United Network for Organ Sharing, which looks for a match based on geography, blood type, age and other factors. Two blood tests confirming the donor’s type are needed before making a match.

In this case, the organs were somehow registered with the national network as having type O blood. In fact, though, the blood was type A.

Whitson, the Ohio State surgeon who was not involved in the South Carolina case, said for a blood typing problem this serious to happen, “there was some error that was pervasive throughout.”

BECOME AN ORGAN DONOR

Signing up to become an organ donor is a process that takes only a few minutes at **www.registerme.org**. Each donor can save up to eight lives.

Vanderbilt University Medical Center in Tennessee and MUSC each accepted offers to transplant the available organs into their patients.

The liver transplant recipient in Tennessee survived the ordeal.

Vanderbilt “complied with all internal and national policies in receiving and transplanting the organ,” a spokesman wrote in a statement. He added the medical center treated the incident as a learning process and has willingly taken part in conversations “to do our part in helping improve the process.”

The same Columbia law firm is representing both Michelle Holliman and the man who received the liver at Vanderbilt. Lucy Dinkins, an attorney with the firm, said the man in Tennessee had to have a second liver transplant to fix the mistake “and continues to suffer serious complications.” No lawsuit has been filed regarding the liver procedure, according to court records.

Michelle first sued We are Sharing Hope SC in July of last year. Her legal team added MUSC and the United Network for Organ Sharing as defendants this spring, and they also filed suit against a surgeon involved in Allen’s care this summer.

A spokeswoman for MUSC said the transplant team in Charleston worked off of the blood type information given by the organ network. They wouldn’t learn of the mismatch until Allen’s body was rejecting the lungs and fighting to survive.

Reporting gone wrong

Despite a state regulation in place requiring hospitals to report all incidents of death or serious injury in patients within 10 days, no one told the South Carolina health department about Allen Holliman’s death, the agency confirmed.

A DHEC spokeswoman said the agency would begin an investigation after the newspaper’s inquiry.

MUSC declined to comment on the lawsuit, which is pending. But spokeswoman Heather Woolwine said in a statement the hospital didn't report Allen's death to DHEC because "the error occurred outside of MUSC Health processes."

"Our transplant team cares deeply about its patients and is heartbroken when a patient's outcome is not successful," she said. "We can say that MUSC Health providers followed the national standard of care."

When the federal government got a complaint stemming from the incident in 2019, its investigators found problems with We are Sharing Hope SC's blood-typing policies. There were no standards in place guiding its team on what to do if there was an inconclusive blood test, according to federal reports provided to The Post and Courier.

The Centers for Medicare & Medicaid Services also cited We Are Sharing Hope SC for failing to disclose the error at Vanderbilt. The organization's director of quality told investigators she forgot to make the report. The federal health authority didn't get a complaint about Holliman's death.



CMS disciplined Vanderbilt University Medical Center after a liver transplant went wrong



CMS disciplined We Are Sharing Hope SC

The hospitals did tell the United Network for Organ Sharing, the national organization that helps match donors and recipients.

Two days after the failed transplants, it sent a memo reminding donor coordinators and every transplant hospital in the country **not to rely on blood tests taken after a transfusion**. And just this summer, a committee issued new guidance **after "recent reports" of mistakes**. A network spokeswoman said she couldn't confirm whether those actions and the South Carolina case were linked.

But she did say "instances of unintended, mismatched blood type transplants are very rare."

The federal Medicare agency explained responsibility is shared throughout the organ donation process. Two people should confirm the donor's information at the regional network. And when the organs arrive at the hospital, the surgeon and another staff member should verify blood types.

Ultimately, the surgeon who puts the donated organ into the patient's body is responsible for making sure his or her patient is matched correctly, a spokesman for the agency said.

We Are Sharing Hope SC resolved its issues with the government last year. It, too, declined to comment on the details of Allen Holliman's case.

"We Are Sharing Hope SC follows the standard of care related to the organ donation practice and we take seriously our responsibility to honor the donation legacy," a spokeswoman said in a statement. "Our sympathies remain with all families who experience the loss of a loved one."

Death at Duke

Courts are filled with medical malpractice lawsuits, stories of scalpels slicing off the mark, patients' complaints ignored and even tools sewn into people's bodies by accident. But with an ultimate gift from a lost life on the line, and another dependent on the organ, little room is left for mistakes.

Jesica Santillan captured national attention in 2003 when her family smuggled her over the border from Mexico, where she lacked the medical care needed to treat her fatal heart disease. Santillan landed at Duke University.

Her surgeon, Dr. James Jaggers, accepted an offer for a set of heart and lungs for Santillan. But there was a miscommunication between Jaggers and the donor coordinator, according to a **U.S. News and World Report article**. The blood types didn't match.

Jaggers didn't discover the problem until the organs were inside his patient. The teenager died after the medical team tried to retransplant another set of the right type.

Major news outlets around the country picked up the story. Duke promised to make its process safer. "Human errors and an insufficient backup system" contributed to her death, leaders said.

Later, Jaggers would say as her surgeon, "I am ultimately responsible for the team and for this error."

The Joint Commission, a governing body that tracks hospital quality, released its Universal Protocol **not long after**, aimed at making all surgeries safer. Before a surgery begins, the team should do a "time-out," the protocol states.

Everyone is supposed to take a beat. The Joint Commission says the surgical team should verify they have the correct patient and are about to do the right procedure. Though the protocol isn't specific to transplants, these nationally recognized standards suggest labeled lab results be displayed in the room.

If a safety problem kills a patient, the Joint Commission strongly encourages the hospital to report the event. Doing so invites an investigation involving commission experts in the hope of keeping the mistake from being repeated.

One kind of incident the commission wants hospitals to report: Incorrect blood typing.

Contacted by The Post and Courier, the Joint Commission said it was not aware of Allen Holliman's death at MUSC. But as a result of the newspaper's inquiry, it said it would start a review. The hospital said it didn't need to make the report, because they maintain it wasn't their mistake.



COVID-19

MUSC doctors perform first blood plasma transfusions in Lowcountry for COVID-19 patients

BY LAUREN SAUSSER LSAUSSER@POSTANDCOURIER.COM

Shared responsibility

Almost 24 hours after Allen Holliman's transplant began, it was clear to his wife something was wrong. He was in critical care.

Michelle Holliman fell into a brief sleep on the couch in the hospital waiting room. She awoke to someone shaking her and a surgeon's pale face as he delivered bad news.

"The answer I got was unbelievable," Michelle said. "I'm still numb."

The medical team apologized, Michelle said. Still, she is angry. She feels she doesn't have the answers she needs, and she knows her husband deserved better.

Nancy Berlinger, a scholar at The Hastings Center, a bioethics think tank in New York, said it should be acknowledged that medicine is never delivered by just one person.

"Safety is created every day by how people work together," Berlinger said.

When a system breaks down, she also said it is important that everyone involved not only apologize, but take responsibility.



NEWS

See inside a SC hospital's 'honor walk' tribute to an organ donor

STAFF REPORTS

Meanwhile, the number of people choosing to become organ donors is on the rise, and Whitson, the Ohio State surgeon, said he wants it to stay that way. People shouldn't use rare cases of fatal mistakes as an excuse to distrust the process, he said, which "is very robust."

In South Carolina, if trends hold true, **We are Sharing Hope SC will** recover organs from more than 100 people this year.

Reach **Mary Katherine Wildeman** at 843-607-4312. Follow her on Twitter @mkwildeman.

MORE INFORMATION

3 Americans win Nobel medicine prize for discovering hepatitis C virus

Organ donation nonprofit faces another suit over blood typing accident that killed SC man

After blood-type error, SC organ network faces investigation, pressure to improve

Pig-to-human transplants come a step closer with new test

MUSC will remove 23 patients from transplant waiting list for failure to get COVID vaccine

MARY KATHERINE WILDEMAN

Mary Katherine, who also goes by MK, covers health care for The Post and Courier. She is also pursuing a master's degree in data science. She grew up in upstate New York and enjoys playing cards, kayaking and the Blue Ridge Mountains.

EXHIBIT B

EXHIBIT C

To: **SFC Majority/Minority Health LA's**
Subject: **Hearing - - "A System in Need of Repair: Addressing Organizational Failures of the U.S.'s Organ Procurement and Transplantation Network"**
Date: **August 3, 2020, 2:30PM**

I. Introduction

On August 3, 2022, at 2:30 p.m. in room 215 of the Dirksen Senate Office Building, the U.S. Senate Committee on Finance (herein referred to as the "Committee") will hold a hearing titled "A System in Need of Repair: Addressing Organizational Failures of the U.S.'s Organ Procurement and Transplantation Network."

The purpose of this hearing is to update Committee members on Chairman Wyden and Senator Grassley's bipartisan investigation into the United Network of Organ Sharing (UNOS) and to share their concerns with UNOS's oversight of the U.S. Organ Procurement and Transplantation Network (OPTN), specifically concerning its policy compliance and patient safety activities related to organ procurement organizations (OPOs).

II. Witnesses

a. Brian Shepard, *CEO, United Network for Organ Sharing (UNOS)*

Brian Shepard has been with UNOS since 2010 and has served as Chief Executive Officer since 2012.[1] On June 28, 2022, UNOS announced that Shepard "will depart the organization at the end of September, following the completion of his contract."[2] Prior to joining UNOS, he served 15 years in various high-level positions in Virginia state government. Shepard is a Virginia native, with a bachelor's degree in history from Virginia Tech and a master's degree in business administration from the University of Virginia.[3]

b. Diane Brockmeier, RN, *President and CEO, Mid-America Transplant*

Diane Brockmeier is the CEO of Mid-America Transplant, an OPO headquartered in St. Louis Missouri. She first joined Mid-American Transplant in 1986 as an organ procurement coordinator, and has been president and CEO since February 2016. As president and CEO of Mid-America Transplant, Brockmeier oversees strategic operations, including key partnerships with more than 120 hospitals and transplant centers located throughout Missouri, northeast Arkansas and southern Illinois.[4] From 2020 to 2022, Brockmeier served as the Chair for the OPTN OPO Committee and was a member of the UNOS board from 2018-2020. She currently serves on the

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[1] *Leadership*, UNITED NETWORK FOR ORGAN SHARING, https://unos.org/about/leadership/brian-shepard/ (last visited July 26, 2022).
[2] *Press Release*, UNITED NETWORK FOR ORGAN SHARING, https://unos.org/news/unos-in-the-news/unos-ceo-brian-shepard-to-leave-organization-after-a-decade-of-service/ (last visited July 26, 2022).
[3] *Leadership*, UNITED NETWORK FOR ORGAN SHARING, https://unos.org/about/leadership/brian-shepard/ (last visited July 26, 2022).
[4] *Press Release*, MID-AMERICA TRANSPLANT, https://www.midamericatransplant.org/news/diane-brockmeier-receives-most-influential-business-women-award (last visited July 26, 2022).

Executive Committee as Treasurer/Secretary of the Association of Organ Procurement Organizations (AOPO) and previously served as the AOPO President from 2018 – 2019.

c. Barry Friedman, RN, *Executive Director at Advent Health Transplant Institute*

Barry Friedman is the Executive Director at Advent Health Transplant Institute, in Orlando Florida. Friedman has over 30 years of clinical/administrative experience in health care. He attended Southern Illinois University, and graduated with a bachelor's in nursing and an MBA with a minor in health care administration. His civilian career Organ Transplantation began in 1984 as an ICU Staff Nurse in St Louis, Missouri. In 1976, he began his military career becoming a commissioned officer in 1985 as an Aeromedical Flight Nurse. He returned to the transplant community as an Organ Procurement Coordinator with Mid America Transplant in 1986. Over his career, Friedman has worked in a variety of roles and leadership positions at transplant centers across the country. From 2012 – 2016 he was the Chief of Clinical Global Services for Minnesota International Medicine, where he consulted in seven countries on matters related to organ transplant and procurement. Currently, he serves as the Executive Director at Advent Health Transplant Institute where he provides regulatory, administrative and fiscal oversight, including on chronic and end stage organ failure, solid organ transplant, and mechanical circulatory support programs.

Friedman is an active member of the transplant community. He has been a member of the American Society of Transplantation (AST), where he served as the Chairperson of Membership and is a past President of the North American Transplant Coordinators Organization (NATCO). He has served on various committees including the Board of Directors at UNOS and the Eastern Missouri National Kidney Foundation. He also has served as the Transplant Coordinator representative for Studies in Pediatric Liver Transplant, SPLIT. He currently serves with UNOS as Chair of the Ad Hoc International Relations Committee.[5]

d. Calvin Henry, *Double lung transplant recipient, Patient Affairs Committee representative*

Calvin Henry is a transplant recipient from Georgia. He received a double lung transplant in 2012 at Houston Methodist Hospital.[6] He was diagnosed with idiopathic pulmonary fibrosis, considered a terminal illness. He has a background in healthcare information. He is currently a Region 3 Representative on the UNOS Patient Affairs Committee.[7] Mr. Henry now runs marathons, most recently completing the Aramco Half Marathon in January of this year, and volunteers as a patient mentor for his local transplant center in Georgia, connecting those on the waitlist with educational and financial resources.

e. Jayme Locke, M.D., MPH, *Director Division of Transplantation, Heersink School of Medicine, University of Alabama at Birmingham (UAB)*

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[5] *Profile*, ORGAN DONATION AND TRANSPLANTATION ALLIANCE, https://www.organdonationalliance.org/profile/barry-friedman/ (last visited July 26, 2022).
[6] *Double lung transplant recipient returns to Houston to run Aramco Half Marathon*, ABC13, Jan. 15, 2020, https://abc13.com/chevron-houston-marathon-aramco-half-double-lung-transplant-runner/11473456/ (last visited July 26, 2022).
[7] *Patient Affairs Committee*, ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK, https://optn.transplant.hrsa.gov/about/committees/patient-affairs-committee/ (last visited July 26, 2022).

Dr. Locke is an abdominal transplant surgeon who specializes in innovative strategies for the transplantation of incompatible organs, disparities in access to and outcomes after solid organ transplantation, and transplantation of HIV-infected end-stage patients. Her research interests include complex statistical analysis and modeling of transplant outcomes and behavioral research focused on health disparities.[8] Locke completed her undergraduate degree at Duke University, her medical degree at East Carolina University and her surgical residency at Johns Hopkins, where she received training in general surgery and multi-visceral abdominal transplantation. Dr. Locke additionally completed her Master of Public Health (MPH) degree while at Johns Hopkins. She joined the surgical faculty at University of Alabama at Birmingham (UAB) after completion of her surgical residency.

Locke is a well-published investigator, authoring 52 articles and 11 book chapters. She currently holds an NIH K23 Career Development Award and a Clinical Science Faculty Development Grant through the American Society of Transplantation. In addition, Locke is an Associate Editor for Transplantation and is a regular peer reviewer for several journals, including the American Journal of Transplantation and the Journal of the American Society of Nephrology to name a few. She is an invited member of the ASTS Providing Better Access to Organs Task Force and Diversity Affairs Committee, the AST Kidney-Pancreas Committee, The Transplantation Society Young Member Committee, and the UNOS Pediatric Transplant Committee.[9]

III. Summary and Findings

As of June, approximately 20,600 organ transplants were performed in the United States for FY2022.[10] However, the high transplant rate, due in part to increased suicide and opioid-related deaths in recent years, masks a myriad of problems within the transplant industry.[11] According to the Health Resources and Services Administration (HRSA), around 6,000 Americans die each year while waiting for organ transplants.[12] This problem is even more acute for people of color and people in rural communities. For example, according to a report by Critical Care Medicine, Black Americans are less likely to be given opportunities to consider donation, contributing to the shortage in available organs.[13] Experts estimate that, by reforming government regulations and

[8] *Faculty*, DEPARTMENT OF SURGERY, HEERSINK SCHOOL OF MEDICINE, UNIVERSITY OF ALABAMA AT BIRMINGHAM, https://www.uab.edu/medicine/surgery/transplantation/faculty/locke (last visited July 26, 2022).
[9] *Faculty*, DEPARTMENT OF SURGERY, HEERSINK SCHOOL OF MEDICINE, UNIVERSITY OF ALABAMA AT BIRMINGHAM, https://www.uab.edu/medicine/surgery/transplantation/faculty/locke (last visited July 26, 2022).
[10] *Data and Trends*, UNOS, https://unos.org/data/ (last visited July 21, 2022).
[11] Brian Owens, *Organ Donations from Overdose Deaths on the Rise but Stigma Remains*, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5988527/. During the course of this investigation, UNOS often cited to increased donation rates to highlight the success of its operations. However, UNOS failed to address the increase in organs discarded, now 25% of kidneys are discarded. *See* Amanda Robinson et al., *Eliminate Use of DSA and Region from Kidney Allocation One Year Post-Implementation Monitoring Report*, (July 1, 2022) https://optn.transplant.hrsa.gov/media/p2oc3ada/data_report_kidney_full_20220624_1.pdf
[12] *Organ Donation Statistics*, HRSA, https://www.organdonor.gov/learn/organ-donation-statistics#glance (last visited July 21, 2022) (According to HRSA, 17 people die each day waiting for an organ transplant.).
[13] Laura A. Siminoff et al, *Comparison of Black and White Families' Experiences and Perceptions Regarding Organ Donation Requests*, 31 Critical Care Medicine 146 (2003). https://journals.lww.com/ccmjournal/Abstract/2003/01000/Comparison_of_black_and_white_families_.23.aspx.

holding OPOs accountable, 28,000 more organs could be transplanted each year.[14] Experts also project that improvements to the OPTN could save the federal government and taxpayers up to $40 billion over the next decade, particularly through reductions in dialysis and treatment of End Stage Renal Disease which accounts for $36 billion in Medicare spending each year.[15]

This bipartisan investigation began in February 2020 when then-Chairman Charles Grassley, then-Ranking Member Ron Wyden, Senator Todd Young, and Senator Benjamin Cardin sent a letter to UNOS expressing their concerns about the adequacy of patient safety standards and belief that OPOs are failing to recover thousands of viable organs each year.[16] The letter also highlighted an investigation by the Department of Health and Human Services, Office of Inspector General (HHS OIG) and news reports, shining a light on "lapses in patient safety, misuse of taxpayer dollars, and tens of thousands of organs going unrecovered or not transplanted," leading to questions about the adequacy of UNOS' oversight of OPOs."[17]

In 2021, the investigation continued under the leadership of now-Chairman Wyden and Ranking Member Grassley of the Senate Judiciary Committee with a series of bipartisan requests for information sent to HHS,[18] CMS,[19] HRSA, and the Office of Management and Budget. Staff also broadened the scope of the investigation to include concerns about the inadequacy of the OPTN information technology system and its impact on patients.

In February 2021, nearly a year into the investigation, the Committee issued a subpoena to UNOS demanding documents in support of the investigation.[20] In response to the subpoena, the Committee received hundreds of thousands of pages of documents and internal memoranda, which helped inform the findings of this investigation. Based on information collected for this investigation, between 2010 and 2020, a total of 1,118 complaints were submitted against all 57 OPOs (some more than others) by various stakeholders, including transplant centers, families,

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[14] *Summary of Findings*, BLOOMWORKS, https://bloomworks.digital/organdonationreform/Summary/#key-findings-and-opportunities (last reviewed July 21, 2022).
[15] *Summary of Findings*, BLOOMWORKS, https://bloomworks.digital/organdonationreform/Summary/#key-findings-and-opportunities (last reviewed July 21, 2022).
[16] Press Release, Finance Committee Members Probe U.S. Organ Transplant System (Feb. 12, 2020), https://www.grassley.senate.gov/news/news-releases/finance-committee-members-probe-us-organ-transplant-system.
[17] Letter to Brian Shepard, Chief Executive Officer of United Network for Organ Sharing, from the Senate Committee on Finance (Feb.10, 2020), https://www.finance.senate.gov/imo/media/doc/2020-02-10%20Grassley,%20Wyden,%20Young,%20Cardin%20to%20UNOS%20(Information%20Request%20on%20Organ%20Transplant%20System).pdf.
[18] Letter to Norris Cochran, Acting Secretary for the Department of Human and Health Services from Senate Committee on Finance (Mar. 16, 2021), https://www.finance.senate.gov/imo/media/doc/031621%20Bipartisan%20Bicameral%20HHS%20OPO%20Rule%20Support%20Letter.pdf.
[19] Letter to Xavier Becerra, Secretary for the Department of Health and Human Services, and Chiquita Brooks-LaSure, Administrator for Centers for Medicare and Medicaid Services, from the Senate Committee on Finance (July 19, 2021), https://www.finance.senate.gov/imo/media/doc/071921%20Wyden%20Grassley%20Young%20Bipart%20Bicam%20OPO%20letter%20to%20HHS.pdf.
[20] Press Release, Grassley, Wyden Subpoena the United Network for Organ Sharing as part of Continued Investigation into U.S. Organ Transplant System (Feb. 4, 2021), https://www.finance.senate.gov/ranking-members-news/grassley-wyden-subpoena-the-united-network-for-organ-sharing-as-part-of-continued-investigation-into-us-organ-transplant-system.

anonymous individuals, UNOS staff, and OPOs themselves.[21] Based on documents and internal memoranda, the Committee found that:

- The OPTN is failing to provide adequate oversight of the nation's 57 OPOs, resulting in fewer organs available for transplant.

- The lack of oversight by UNOS causes avoidable failures in organ procurement and transplantation resulting in risks to patient safety. These failures include testing procedure errors, transportation issues resulting in life saving organs being lost or destroyed in transit, and process and procedure failures.

- UNOS lacks technical expertise to modernize the OPTN IT system, resulting in risk of system interruption or technical failure with the potential to harm patients across the country.

IV. Background

a. Establishment of the OPTN

Following the passage of the National Organ Transplant Act (NOTA) in 1984, the Secretary of HHS established, by contract, a national computerized system for matching patients with organs, referred to as the Organ Procurement and Transplantation Network (OPTN).[22] NOTA provides grants to OPOs and established the first national network to facilitate matching deceased donor organs to transplant candidates.[23] Today, the OPTN has over 391 members, including 252 transplant centers and 57 OPOs.[24] UNOS was awarded the first OPTN contract in 1986 and has received all seven subsequent contract awards for the OPTN.[25]

b. The OPTN Contract

By law, the OPTN is operated under contract between HHS and a non-profit entity with expertise in organ donation and transplantation. UNOS is the only contractor to ever hold, or bid for, the OPTN contract. Under the OPTN contract with HHS, UNOS performs the following functions:[26]

1. Supporting the operating and governance activities of the OPTN Board of Directors;
2. Maintaining the national OPTN waiting list of individuals in need of one or more organ(s) for transplantation;

[21] Document on file with Committee.
[22] 42 U.S.C. §274.
[23] 42 U.S.C. §273.
[24] *Organ Procurement & Transplantation Network*, https://optn.transplant.hrsa.gov/about/ (last visited July 21, 2022).
[25] *Organ Procurement & Transplantation Network*, https://optn.transplant.hrsa.gov/about/ (last visited July 21, 2022).
[26] 42 U.S.C. §273(a)(2).

3. Matching organs to individuals on the national OPTN waiting list;
4. Supporting, establishing, and enforcing OPTN membership criteria for member entities and designated transplant program requirements;
5. Conducting reviews and evaluations of OPTN members and taking actions consistent with the OPTN final rule and the OPTN Bylaws for OPTN member non-compliance, including referring matters to the Secretary;
6. Developing policies for the allocation of donated organs and other policies authorized by the OPTN final rule consistent with the OPTN final rule;
7. Maintaining a twenty-four-hour system to facilitate organ-recipient matching;
8. Assisting OPOs in the nationwide distribution of organs;
9. Collecting, analyzing, and publishing organ donation and transplantation data; and,
10. Working actively to increase the supply and utilization of donated organs.

As highlighted above, UNOS was awarded the first OPTN contract in 1986 and has since received all seven contract awards for the OPTN.[27] In September 2021, the OPTN estimated that the annual operating costs would be approximately $63.9 million.[28] Of this figure, approximately $6.5 million is from federally appropriated funds and the remainder comes from OPTN registration fees.[29] The OPTN registration fee is collected by UNOS from transplant centers when they add a patient to the OPTN waiting list.[30] As of FY2022, the OPTN registration fee was $868.[31] The cost to operate the OPTN in 2023 is estimated to increase to $72,482,500, and the patient registration fee is proposed to be $944.[32] In addition to these fees, UNOS also charges additional fees, separately from the registration fee, for providing data, support services, transportation, conferences, and educational materials to OPOs and to outside parties.[33]

c. Organ Procurement Organizations

OPOs are not-for-profit organizations responsible for the procurement of organs for transplantation in the United States.[34] OPOs are responsible for working with donor hospitals to identify opportunities for organ donation, working with donor families to obtain consent for organ donation, when necessary, conducting testing to identify potential for disease transmission or other

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[27] *Organ Procurement & Transplantation Network*, https://optn.transplant.hrsa.gov/about/ (last visited July 21, 2022).
[28] *OPTN Budget and OPTN Registration Fee Set for New Fiscal Year*, September 2, 2021. https://optn.transplant.hrsa.gov/news/optn-budget-and-optn-registration-fee-set-for-new-fiscal-year/.
[29] *OPTN Budget and OPTN Registration Fee Set for New Fiscal Year*, September 2, 2021. https://optn.transplant.hrsa.gov/news/optn-budget-and-optn-registration-fee-set-for-new-fiscal-year/.
[30] *OPTN Budget and OPTN Registration Fee Set for New Fiscal Year*, September 2, 2021. https://optn.transplant.hrsa.gov/news/optn-budget-and-optn-registration-fee-set-for-new-fiscal-year/.
[31] *OPTN Budget and OPTN Registration Fee Set for New Fiscal Year*, September 2, 2021. https://optn.transplant.hrsa.gov/news/optn-budget-and-optn-registration-fee-set-for-new-fiscal-year/.
[32] *Organ Procurement and Transplantation Network: OPTN Charter*,https://optn.transplant.hrsa.gov/about/optn-charter/#:~:text=This%20Charter%20governs%20the%20structure,Act%2C%20as%20amended%2C%2042%20U.S.C.(last viewed July 21, 2022).
[33] United Network for Organ Sharing, *Financial Statements and Supplementary Information*, (2021), at 4, https://unos.org/wp-content/uploads/2021-Audited-Financial-Statement.pdf.
[34] United Network for Organ Sharing, *Increasing Organ Donation*, https://unos.org/transplant/opos-increasing-organ-donation/ (last viewed July 21, 2022).

safety issues, and safely procuring and transporting all transplantable organs based on OPTN policies.[35] There are 57 OPOs and each is assigned a donor service area (DSA) covering every potential donor hospital in the country.[36]

At the time that NOTA was enacted, OPOs had already existed and received payment for activities under Medicare. They arose organically, first as organ banks to preserve organs within a hospital's transplant center. These organ banks eventually coordinated organ sharing among multiple transplant centers, especially when an organ would have otherwise gone unused at the hospital that the organ bank was affiliated with. As the organ banks' functions grew, they became independent entities, evolving into the OPOs as they function today.

d. Federal Regulation and Oversight of the OPTN

HHS promulgated regulations to establish the structure and operations of the OPTN in 1998. These regulations are known as the OPTN final rule.[37] The final rule was delayed several times, but ultimately went into effect in March 2000.[38] There was no regulatory framework in the period between enactment of NOTA and the final rule. The OPTN was governed solely by NOTA statutory requirements and the terms of the OPTN contract.

The Division of Transplantation within the Health Systems Bureau of HRSA is the primary entity responsible for oversight of the OPTN.[39] Under NOTA, OPOs and transplant hospitals participating in Medicare and Medicaid must be members of the OPTN.[40] The OPTN board of directors, with the advice of the OPTN membership, is responsible for developing policies for organ allocation and donation.[41] However, in order for an OPTN policy to become enforceable, the OPTN must submit the policy for approval to the Secretary of HHS at least 60 days prior to the proposed implementation date.[42] OPTN policies are not enforceable until approved by the Secretary.[43]

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[35] U.S. Centers for Medicare and Medicaid Services, *Organ Procurement Organization (OPO) Conditions for Coverage Final Rule: Revisions to Outcome Measures for OPOs CMS-3380-F*, (Nov. 20, 2020), https://www.cms.gov/newsroom/fact-sheets/organ-procurement-organization-opo-conditions-coverage-final-rule-revisions-outcome-measures-opos.

[36] United Network for Organ Sharing, *Increasing Organ Donation*, https://unos.org/transplant/opos-increasing-organ-donation/ (last viewed July 21, 2022).

[37] 42 C.F.R. Part 121.

[38] 65 C.F.R. § 15252. The OPTN final rule also established: 1) requirements for the structure and responsibilities of the OPTN Board of Directors; 2) minimum requirements for listing transplant candidates; 3) minimum expectations for organ procurement and testing; 4) minimum requirements for packaging and transportation of organs; 5) high-level goals for organ allocation policies; and 6) authority for review, evaluation of OPTN members and enforcement of OPTN rules. *Id.*

[39] *Health Systems Bureau*, HRSA https://www.hrsa.gov/about/organization/bureaus/hsb/index.html (last viewed July 21, 2022).

[40] 42 C.F.R. § 121.3(b).

[41] 42 C.F.R. § 121.4(a).

[42] 42 C.F.R. § 121.4(b)(2).

[43] 42 C.F.R. § 121.4(b)(2).

Although the OPTN operates under a contract from HRSA, OPOs are certified by CMS every 4 years.[44] If an OPO fails to meet conditions for coverage, it must submit an acceptable plan of correction or risk decertification. However, despite historical underperformance and records of deficiencies in policy compliance and patient safety, no OPO has ever been decertified by the federal government.[45] Additionally, CMS also maintains Conditions of Coverage for transplant hospitals.[46] These conditions establish the requirements for OPOs and transplant centers to participate in and receive payment under Medicare and Medicaid.

In November 2020, CMS issued a final rule changing the methodology used to evaluate OPO performance (the "OPO final rule").[47] This rule followed former President Trump's Executive Order on "Advancing American Kidney Health," and its stated policy is to prevent kidney failure, increase choice for patients with end-stage renal disease, and to modernize organ recovery and transplantation in the United States.[48] On January 20, 2021, President Biden's Administration issued a memo requesting that all rules, guidance, or agency actions which did not take effect prior to January 20, 2021 be delayed to provide agency officials with the opportunity for further review of the issues of fact, law, and policy raised by such rules.[49] Subsequently, CMS provided an additional 30-day comment period for the OPO final rule, which then became effective March 30, 2021.[50] The OPO final rule applied two new outcome measures, a donation rate measure, and a transplantation rate measure.[51] For example, CMS plans to use death certificate information obtained by the Centers for Disease Control to measure OPO performance.[52] CMS explained that this change is necessary because:

> "[C]urrent OPO outcomes measures are not sufficiently objective and transparent to ensure appropriate accountability in assessing OPO performance, nor do they properly incentivize the adoption of best practices and optimization of donation and organ placement rates."

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[44] *Organ Procurement Organization Final Rule Takes Effect*, FOLEY & LARDNER LLP (Apr. 14, 2021), https://www.foley.com/en/insights/publications/2021/04/organ-procurement-organization-final-rule-effect#:~:text=CMS%20conducts%20OPO%20performance%20surveys,of%20correction%20or%20risk%20decertification.

[45] *Oversight*, Bloomworks, https://bloomworks.digital/organdonationreform/Oversight/ (last viewed July 21, 2022).

[46] 42 C.F.R. Parts 413, 441, 486 and 498.

[47] U.S. Centers for Medicare and Medicaid Services, *Organ Procurement Organization (OPO) Conditions for Coverage Final Rule: Revisions to Outcome Measures for OPOs CMS-3380-F*, (Nov. 20, 2020), https://www.cms.gov/newsroom/fact-sheets/organ-procurement-organization-opo-conditions-coverage-final-rule-revisions-outcome-measures-opos.

[48] Exec. Order No. 13879, 3 C.F.R. 247 (2007), https://www.federalregister.gov/documents/2019/07/15/2019-15159/advancing-american-kidney-health.

[49] MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES (Jan. 20, 2021), https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/regulatory-freeze-pending-review/.

[50] 42 C.F.R. Parts 486.

[51] U.S. Centers for Medicare and Medicaid Services, *Organ Procurement Organization (OPO) Conditions for Coverage Final Rule: Revisions to Outcome Measures for OPOs CMS-3380-F* https://www.cms.gov/newsroom/fact-sheets/organ-procurement-organization-opo-conditions-coverage-final-rule-revisions-outcome-measures-opos.

[52] 42 CFR Part 486 at 36, https://www.cms.gov/files/document/112020-opo-final-rule-cms-3380-f.pdf.

Based on 2018 data, CMS estimated that 22 of the 57 OPOs would fall into "Tier 3" status, meaning that they would fail the new outcome measures and be decertified.[53] However, in its current form the rule does not provide for decertification of OPOs until 2026.[54]

V. Investigative Findings and Concerns

a. OPOs Continue to Underperform

As explained in greater detail above, CMS estimated that, under the OPO final rule, 22 of the 57 OPOs would fail the new outcome measures and be decertified.[55] Meanwhile, around 6,000 Americans die each year while waiting for an organ transplant.[56] Based on the findings of this investigation, OPO underperformance and lack of improvement incentives contribute to these shortcomings. In fact, CMS estimated that, if OPOs increased their performance, approximately 5,600 more organs per year could be transplanted.[57]

According to HRSA, the number of patients awaiting organ transplantation far outstrips the supply of donated organs, and every ten minutes, another person is added to the national waitlist. These problems continue despite reporting that OPOs are failing to recover thousands of viable organs each year. In fact, Kaiser Health News reports that organs recovered often do not get transplanted due to OPO errors stating that "a startling number of lifesaving organs are lost or delayed while being shipped on commercial flights, the delays often rendering them unusable."[58]

Based on information collected for this investigation, between 2010 and 2020, a total of 1,118 complaints were submitted against all 57 OPOs (some more than others) by various stakeholders, including transplant centers, families, anonymous individuals, UNOS staff, and OPOs themselves.[59] Furthermore, the HHS Office of the Inspector General (OIG), Federal Bureau of Investigation, and others have identified inappropriate use of Medicare funds by OPOs, along with other illegal financial arrangements, ranging from seeking reimbursement for unallowable and unsupported expenditures on activities such as entertainment, meals, lobbying, and donations and gifts to an illegal kickback scheme between an OPO and a local funeral home, which led to

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[53] 42 CFR Part 486 at 59, https://www.cms.gov/files/document/112020-opo-final-rule-cms-3380-f.pdf.
[54] U.S. Centers for Medicare and Medicaid Services, *Organ Procurement Organization (OPO) Conditions for Coverage Final Rule: Revisions to Outcome Measures for OPOs CMS-3380-F* https://www.cms.gov/newsroom/fact-sheets/organ-procurement-organization-opo-conditions-coverage-final-rule-revisions-outcome-measures-opos.
[55] U.S. Centers for Medicare and Medicaid Services, *Organ Procurement Organization (OPO) Conditions for Coverage Final Rule: Revisions to Outcome Measures for OPOs CMS-3380-F* https://www.cms.gov/newsroom/fact-sheets/organ-procurement-organization-opo-conditions-coverage-final-rule-revisions-outcome-measures-opos.
[56] Health Resources and Services Administration, *Organ Donation Statistics*, https://www.organdonor.gov/learn/organ-donation-statistics#glance.
[57] U.S. Centers for Medicare and Medicaid Services, *Organ Procurement Organization (OPO) Conditions for Coverage Final Rule: Revisions to Outcome Measures for OPOs CMS-3380-F* https://www.cms.gov/newsroom/fact-sheets/organ-procurement-organization-opo-conditions-coverage-final-rule-revisions-outcome-measures-opos.
[58] JoNel Aleccia, *How Lifesaving Organs for Transplant Go Missing in Transit*, KHN (Feb. 10, 2020), https://khn.org/news/how-lifesaving-organs-for-transplant-go-missing-in-transit/.
[59] On file with the Committee.

the OPO leadership serving time in federal prison. The complaints concern a variety of issues, including data entry, labeling, packaging, and organ allocation, as well as process and procedure errors.

Testing Failures – Between 2010 and 2020, 104 complaints were submitted to UNOS regarding "testing procedure" errors.[60] These complaints include issues like donor blood type mix ups (referred to as ABO incompatibility), infectious diseases not identified pre-transplant, or required blood and urine tests not being completed on the donor pre-transplant.[61] More specifically, from January 2008 to September 2015, 211 donors transmitted disease and 249 total recipients developed donor derived disease. From these 249 transmissions, 70 died from donor-derived disease.[62] This data illustrates the lethality of diseases contracted during a transplantation and the need for exacting scrutiny of such transmissions. Of the patients that developed a disease from their donor's organ, 28% of them died.[63]

The investigation identified several examples of cases illustrative of these testing failures and their impact on patient safety:

1. ABO Incompatibility Case 1 (Donor Network West,[64] San Francisco, CA) – In December 2020, one transplant recipient nearly died after receiving an organ with the wrong blood type and two recipients required the transplanted organs be removed to avoid fatal risks.[65]

2. ABO Incompatibility Case 2 (We Are Sharing Hope,[66] Charleston, SC) – On November 28, 2018, a transplant recipient died after receiving an organ with the wrong blood type.[67]

3. Cancer Transmission Case 1 (Life Connection of Ohio,[68] Kettering, OH) – On June 4, 2020, during a routine follow up, a transplant recipient was told that he had accidentally received a transplant from a donor with cancer. The recipient was told by his surgeon he "may likely die within 3 years."[69]

4. Cancer Transmission Case 2 (LifeQuest Organ Recovery Services,[70] Gainesville, FL) – On February 18, 2018, a transplant recipient contracted cancer unknowingly from a donor. A year later, a germ cell tumor was discovered during a routine transplant follow up appointment.[71]

[60] On file with the Committee.
[61] On file with the Committee.
[62] UNOS_2_000003539, at 3552-3553.
[63] UNOS_2_000003539, at 3552-3553.
[64] Services most of Northern California.
[65] See Appendix A.
[66] Services most of South Carolina.
[67] See Appendix B.
[68] Services Northwest Ohio.
[69] See Appendix C.
[70] Services Northern Florida.
[71] See Appendix D.

5. Kidney Death Case (Nevada Donor Network,[72] Las Vegas, NV) – On July 14, 2017, two kidney transplant recipients contracted a rare infection after transplant surgery. One recipient died days later.[73]

Transportation Failures – Between 2010 and 2020, 53 complaints were submitted to UNOS regarding "transportation" failures.[74] These complaints include incidents that negatively impact the organ's quality or expected arrival time to the transplant center. Below are failures exemplifying complaints that impacted patient safety:

1. Courier Case 1 (Mississippi Organ Recovery Agency,[75] Flowood, MS) – On February 25, 2017, two incidents were reported to UNOS where the courier service requested by the OPO did not arrive in time to get the organs to their flight. This resulted in three cancelled transplants and one discarded kidney.[76]

2. Courier Case 2 (Donor Alliance,[77] Denver CO) – On March 28, 2018, a courier did not pick up all of the organs it was instructed to transport due to a lack of communication. The kidney was subsequently declined by the transplant center due to the delay.[78]

3. Airline Case 1 (We Are Sharing Hope,[79] Charleston, SC) – On September 15, 2015, an organ missed two flights, resulting in the transplant center declining the organ due to increased cold ischemic time (CIT). CIT determines whether a kidney remains viable on ice without blood flow.[80]

4. Airline Case 2 (We Are Sharing Hope,[81] Charleston, SC) – On March 6, 2017, an organ missed the flight to a transplant center. Due to the delay, the organ experienced such prolonged CIT that the transplant surgeon determined it was not viable and had to be discarded.[82]

Process and Procedure Failures – Between 2010 and 2020, 109 complaints were submitted to UNOS regarding "recovery procedures."[83] Below are failures exemplifying complaints that impacted patient safety:

[72] Services most of Nevada.
[73] See Appendix E.
[74] On file with the Committee.
[75] Services most of Mississippi.
[76] See Appendix F.
[77] Services Colorado and most of Wyoming.
[78] See Appendix G.
[79] See Appendix H.
[80] See Appendix H.
[81] See Appendix I.
[82] See Appendix I.
[83] On file with the Committee.

1. Allocation Error Case (LifeGift Organ Donation Center,[84] Houston, TX) – Multiple instances reported between 2018 and 2019 of an OPO not following the heart lung allocation procedures in place, resulting in one instance of a discarded heart.[85]

2. Donation after Circulatory Death Case 1 (Indiana Donor Network,[86] Indianapolis, IN) – On February 24, 2017, an anonymous complaint submitted to UNOS alleged that, when the Operating Room team opened the donor surgically, the donor's heart was still beating. Death was not declared until 10 minutes later.[87]

3. Donation after Circulatory Death Case 2 (Life Alliance Organ Recovery Agency,[88] Miami, FL) – On November 28, 2018, Life Alliance Recovery Organization (FLMP) in Miami, FL recovered organs from a donor before the donor's heart stopped and against the family's wishes. The family had only consented for Donation after Cardiac Death (DCD).[89]

4. Kidney Trash Case (Indiana Donor Network, Indianapolis, IN) – On June 12, 2020, OPO staff accidentally threw a kidney in the trash after procurement, rendering it not sterile and, therefore, not usable.[90]

Failures Outside of OPTN Policy Between 2010 and 2020, 58 complaints were submitted to UNOS defined as "Other" and 28 defined as "Non-Issue."[91] Below is an example of a complaint that fell outside of OPTN policies.

1. Financial Allegations Case (Alabama Organ Center,[92] Birmingham, AL) – In February 2011, UNOS received a complaint from a former OPO staff member who alleged the Executive Director had participated in money laundering and financial improprieties, calling the profits "blood money."[93] These individuals were eventually sentenced to prison.[94]

b. OPTN/UNOS Failing to Provide Adequate Oversight

Under the OPTN contract, UNOS is responsible for establishing membership criteria and policies for the safe and efficient operation of the OPTN.[95] This role is largely addressed through the work of the OPTN Membership and Professional Standards Committee (MPSC), which is

[84] Services parts of Texas, including the Houston area and Northern Texas.
[85] See Appendix J.
[86] Services most of Indiana.
[87] See Appendix K.
[88] Services the Southern tip of Florida.
[89] See Appendix L.
[90] See Appendix M.
[91] On file with the Committee.
[92] Services Alabama.
[93] See Appendix N.
[94] Press Release, Dep't of Justice, Former Alabama Organ Center Executive Sentenced for Fraud (May 16, 2012), https://archives.fbi.gov/archives/birmingham/press-releases/2012/former-alabama-organ-center-executive-sentenced-for-fraud.
[95] *About*, https://optn.transplant.hrsa.gov/about/ (last viewed July 21, 2022).

supported by staff in the UNOS Department of Member Quality.[96] The MPSC is made up of approximately 38 to 42 volunteers with expertise in organ transplant and procurement from more than 11 regions across the country.[97] According to the OPTN website, "the MPSC maintains membership criteria and monitors OPTN member compliance with OPTN membership criteria, OPTN bylaws and policies, and the OPTN Final Rule."[98] Most importantly, the MPSC reviews patient safety risks and provides feedback to OPOs and other members to improve performance and compliance with OPTN rules.

The MPSC takes action or makes recommendations for further action to the OPTN Board of Directors as needed. However, the complaint process is not transparent, as the MPSC only examines cases that UNOS staff refers to it. UNOS staff will refer a case if "any potential patient safety or policy or bylaw noncompliance may exist."[99]Additionally, staff use the HRSA "Wakefield" Criteria to determine when a case needs to be escalated to HRSA, the UNOS board, and the MPSC. However, "a report will also not become a case if it solely pertains to something outside of the OPTN's authority," or if it does not violate a policy.[100] In some years, less than half of safety events identified by UNOS are referred to the MPSC. MPSC findings are not publicly disclosed. Additionally, UNOS does not follow up regarding the outcomes with the individuals who submitted the complaints.

The OPTN website also states that through peer review the MPSC:[101]

1. Reviews events identified as presenting a risk to patient safety, public health or the integrity of the OPTN;
2. Evaluates and supports OPTN members by providing feedback on and recommendations to improve members' performance, compliance, and quality systems; and,
3. Reviews applications for membership in the OPTN, approval of designated transplant programs, and changes in OPTN member key personnel.

The MPSC also:

1. Identifies opportunities for transplant community education to improve patient safety and safeguard the integrity of the transplant system, often through

[96] *Membership & Professional Standards Committee (MPSC)*, https://optn.transplant.hrsa.gov/about/committees/membership-professional-standards-committee-mpsc/ (last reviewed July 21, 2022).
[97] *Membership & Professional Standards Committee (MPSC)*, https://optn.transplant.hrsa.gov/about/committees/membership-professional-standards-committee-mpsc/ (last reviewed July 21, 2022).
[98] *Membership & Professional Standards Committee (MPSC)*, https://optn.transplant.hrsa.gov/about/committees/membership-professional-standards-committee-mpsc/ (last reviewed July 21, 2022).
[99] UNOS Presentation to Investigative Staff of the Senate Finance Committee – UNOS Process for reviewing OPOs.
[100] UNOS Presentation to Investigative Staff of the Senate Finance Committee – UNOS Process for reviewing. OPOs.
[101] *Membership & Professional Standards Committee (MPSC)*, https://optn.transplant.hrsa.gov/about/committees/membership-professional-standards-committee-mpsc/ (last reviewed July 21, 2022).

dissemination of successful examples of membership engagement and sharing of best practices; and,

2. Develops bylaws and policies related to membership criteria or the oversight responsibilities of the MPSC that align with the OPTN mission to maximize organ supply, provide efficient and safe care, and provide equitable access to transplantation.

On June 2, 2022, Chairman Wyden and Senator Grassley's staff interviewed Jacqui O'Keefe, Director of Member Quality at UNOS.[102] As Director of Member Quality, Ms. O'Keefe manages a staff of approximately 65 people from different functional areas within UNOS, including site surveyors, compliance, allocation, and membership, whose job is to support the MPSC.[103] According to Ms. O'Keefe, her team reviews patient safety complaints submitted to UNOS and then refers some, but not all, of those cases to the MPSC for further review.

During her interview, staff asked Ms. O'Keefe how patient safety cases are elevated to the MPSC. Ms. O'Keefe explained that patient safety cases are often submitted to UNOS via its UNet patient safety portal. She further explained that, when a patient safety case is entered into the system, a patient safety analyst reviews the information, requests additional information from the member, and then discusses with their manager on its disposition. The case is then forwarded to a multidisciplinary group, which includes UNOS's Chief Medical Officer, who decides if the case should be forwarded to the MPSC for further review. If the case is elevated to the MPSC, the patient safety analyst compiles staff summaries, patient records, and prior MPSC recommendations to help inform the MPSC's decision. According to Ms. O'Keefe, it takes approximately 2-3 months to complete this process before the MPSC reviews the case.

During this investigation, staff found that, in recent years, less than half of patient safety events identified by Ms. O'Keefe's team were referred to the MPSC. For example, of the 1,118 complaints, 444 complaints were referred to the MPSC (40% of cases) and 674 complaints were not referred to the MPSC (60% of cases).[104] To illustrate even further:

1. 104 complaints were submitted to UNOS regarding "testing procedure" errors.[105] Approximately 70% were not referred to the MPSC.[106]

2. 53 complaints were submitted to UNOS regarding "transportation" errors.[107] Approximately 94% were not referred to the MPSC.[108]

[102] *Jacqueline O'Keefe*, https://unos.org/about/leadership/jacqueline-okeefe/ (last viewed July 21, 2022).
[103] Ms. O'Keefe interview was informal and not transcribed. However, staff took detailed notes which helped form the basis for their findings.
[104] Document on file with Committee.
[105] Document on file with Committee.
[106] Document on file with Committee.
[107] Document on file with Committee.
[108] Document on file with Committee.

3. 109 complaints were submitted to UNOS regarding "recovery procedure" errors.[109] Approximately 83% were not referred to the MPSC.[110]

4. 58 complaints were submitted to UNOS defined as "Other" and 28 defined as "Non-Issue."[111] Approximately 90% did not get referred to the MPSC and of the "Non-Issue" complaints only 1 case was referred to the MPSC.[112]

5. Of the 444 complaints referred to the MPSC:
    a. 1 case resulted in "Probation,"
    b. 3 cases resulted in "Peer Visit,"
    c. 63 cases resulted in a "Letter of Warning" or "Letter of Reprimand,"
    d. 298 cases resulted in "Notice of Noncompliance" or "Uncontested Violation," and,
    e. 68 cases were "Closed with No Action." (It is important to note that the only public adverse actions are "Probation" and "Member Not in Good Standing.")

Staff also observed that certain stakeholders' complaints were more likely to be referred to the MPSC than others. For example, UNOS staff and self-reports were more likely to be referred to the MPSC than anonymous and patient family complaints.

During Ms. O'Keefe's interview, Senator Grassley's staff also asked how the MPSC addresses recurring and systemic patient safety issues (i.e., repeated transportation failures or ABO incompatibility issues). Ms. O'Keefe said that these issues help inform OPTN policy changes, but that it was not the MPSC's job to address broader trends in OPO non-compliance. Instead, Ms. O'Keefe suggested broader trends in non-compliance are forwarded to the Operations and Safety Committee (OSC) for further review.

On June 23, 2022, Chairman Wyden and Senator Grassley's staff interviewed Chris Curran, Chair of the OSC. (Mr. Curran's term ended approximately one week after staff conducted this interview.) According to the OPTN website, the OSC "seeks to improve quality, safety, and efficiency of the organ transplant system [. . .] and reviews de-identified transplant and donation-related adverse events and near misses reported to the OPTN."[113] According to Mr. Curran, the OSC fulfills its mission through policy work, but underscored that the OSC is not an enforcement body. Senator Grassley's staff asked Mr. Curran how the OSC addresses recurring and systemic patient safety issues. Mr. Curran responded that individual cases are not referred to OSC. Instead, OSC uses de-identified data to consider changes to existing OPTN policy and procedures. Mr. Curran also stated that certain issues, like disease transmission,[114] are sent to other committees within UNOS and that UNOS's board has broader oversight of net trends.

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[109] Document on file with Committee.
[110] Document on file with Committee.
[111] Document on file with Committee.
[112] Document on file with Committee.
[113] *Operations & Safety Committee*, https://optn.transplant.hrsa.gov/about/committees/operations-safety-committee/ (last viewed July 21, 2022).
[114] *Ad Hoc Disease Transmission Advisory Committee*, https://optn.transplant.hrsa.gov/about/committees/ad-hoc-disease-transmission-advisory-committee/ (last viewed July 21, 2022).

The Committee's investigation shows that despite the efforts of UNOS and its internal committees, OPOs continue to experience recurring and systemic patient safety issues, including packaging and labeling errors, transportation failures, failure to identify transmissible diseases in donors, and even allegations of fraud. Each of these errors has the potential to have deadly impacts. However, UNOS seems focused on making OPTN policy changes rather than conducting actual oversight of OPOs and other members, including conducting root cause analyses, providing community education on OPTN policies and procedures, or providing support to rectify problems at OPOs. Instead, based on staff's impression, UNOS points fingers and suggests it is up to the OPOs or the federal government to fix the failures of its membership.

c. UNOS IT System Failures and Safety Concerns

While not the sole focus of the Committee's investigation, Senator Grassley and Senator Wyden's staff also heard concerns from patients, transplant center staff, and OPO staff that UNOS lacks technological expertise or the willingness to develop and maintain an adequate IT infrastructure. Staff also heard concerns that the archaic IT system results in delays in placing organs, organs being discarded, and inaccurate data being used to place organs because of its dependence on staff manually entering hundreds of donor and transplant candidate data points rather than upgrading to systems better able to transfer data across Electronic Medical Record platforms.

These concerns were validated in a report from the independent U.S. Digital Service (USDS), which is housed within the Executive Office of the President and provides consultation services to federal agencies on information technology.[115] The report, titled *Lives Are at Stake*, states that UNOS has been able to wiggle through and around most new contract requirements for the OPTN technology by hand-waving at change with technical jargon, while making no substantive progress. The USDS also states that:[116]

- UNOS is incapable of modernizing the OPTN IT infrastructure;
- the core systems are fragile;
- OPTN technology limits policy development;
- UNOS is resistant to change; and,
- OPTN system is dependent on a disjointed and inadequate user experience.

Ultimately, USDS determined that these technological failings are in fact placing lives at stake and recommended that HHS take action to create a better organ transplant system and enable better patient outcomes, including updating NOTA to create flexibility in how the OPTN is serviced by contractors.

VI. Resistance to Requests for Information and a Valid Subpoena

[115] U.S. DIGITAL SERVICE, LIVES ARE AT STAKE – THE GOVERNMENT'S ROLE IN MODERNIZING THE OPTN (Jan. 5, 2021).
[116] U.S. DIGITAL SERVICE, LIVES ARE AT STAKE – THE GOVERNMENT'S ROLE IN MODERNIZING THE OPTN. (Jan. 5, 2021).

Throughout the course of the Committee's investigation, UNOS sought to withhold documents relevant to the Committee's inquiry. In response to requests for information in February and July 2020, UNOS CEO Brian Shepard asserted that "[w]e are sincere in our desire to support the committee's [sic] work by providing meaningful information in a helpful form."[117] Yet, in the same letter, UNOS provided only partial responses to the Committee's questions, citing "obligations to the hospital and OPO members who participate in our peer review processes."[118] Shepard raised a similar concern in an August 4, 2020 email to Committee staff, asking that the Committee "exhaust all the other ways of reviewing this information that would leave the confidential peer review process in place," but also conceded that UNOS "fully [understood] that the Committee is ultimately able to access those identified records through a request of the Secretary of HHS or by subpoena."[119]

Yet, even after the Committee issued a subpoena to UNOS on February 3, 2021, UNOS continued to withhold relevant information from the Committee without asserting a recognized constitutional, federal statutory, or federal common-law privilege applicable in response to a valid federal subpoena. On August 3 2021, one year after Mr. Shepard acknowledged that a valid subpoena would require UNOS to provide information relevant to the Committee's investigation, UNOS continued to produce information with "limited redactions for material that is protected by the peer-review privilege and that also implicates the privacy interests of organ donors or members' staff."[120]

These redactions included the names of OPOs; names of senior OPO employees; time zones, addresses, and other contextual information; and, information that appears to be public information, like the names of presenters at open sessions of an UNOS conference. In some instances, donor IDs appear to be redacted, significantly inhibiting the Committee's ability to analyze the information provided. Ultimately, the Committee only received information necessary to its investigation after repeatedly demanding it from UNOS counsel in a series of written and verbal communications.

VII. Conclusion

From the top down, the U.S. transplant network is not working, putting Americans' lives at risk. The Committee found:

- The OPTN is failing to provide adequate oversight of the nation's 57 OPOs resulting in fewer organs available for transplant.
- The lack of oversight of OPOs by UNOS causes avoidable failures in organ procurement and transplantation resulting in risks to patient safety. These failures include testing procedure errors, transportation issues resulting in life saving organs being lost or destroyed in transit, and process and procedure failures.

[117] On file with Committee.
[118] On file with Committee.
[119] On file with Committee.
[120] On file with Committee.

- UNOS lacks technical expertise to modernize the OPTN IT system resulting in the risk of system interruption or technical failure with the potential to harm patients across the country.

VIII. Recommendations:

Based on the investigation's findings, Committee staff makes the following recommendations to improve the OPTN:

- Remove barriers to competition by removing the specific requirement for HHS to contract only with a "non-profit entity that has an expertise in organ procurement and transplantation;"

- Increase the pool of potential bidders by clarifying that the OPTN functions described in NOTA and subsequent amendments may be operated by more than one contractor, since few contractors will have adequate clinical knowledge and expertise in IT, policy development, and data collection and reporting, and policy compliance activities;

- Promote innovation in all OPTN functions (e.g., policy development, compliance and patient safety mentoring, IT infrastructure, coordinating transport of organs, etc.) as the best qualified entities with distinct skill sets could compete for contracts for these functions;

- Remove a major barrier for entry for bidders by providing authority for HHS to procure a government owned, contractor operated modern IT system to facilitate the OPTN functions;

- Increase security and innovation in the OPTN system by ensuring the new IT system is based on current technologies and operated and maintained by a contractor with adequate IT knowledge and experience;

- Ensure the continued viability of the OPTN by authorizing HHS to collect fees from transplant hospitals when adding a patient to the national organ transplant waitlist. This would replace a current fee structure authorized by regulation which is not flexible enough to provide funding for multiple contracts;

- Increase transparency and accountability for chain of custody and transportation of organs procured for transplant by providing for public reporting, as appropriate, on the status of organs in transport; and,

- Increase accountability for organs lost, damaged, or delayed in transport by requiring oversight and corrective action for such incidents.

APPENDICES A – N

APPENDIX A
Donor Network West (CADN)
Re: Testing Failures and Process Failures

On December 23, 2020, CADN recovered multiple organs (heart, kidney, pancreas, and kidney) from a 15-year-old donor.[121] According to internal UNOS correspondence, the donor suffered gunshot wounds and died after receiving multiple ABO O blood transfusions.[122] CADN staff assigned blood type O to the donor, despite mixed results and ABO typing discrepancies.[123] Post-transplant, it became clear that the donor was actually blood type B.[124] As a result, three recipients, except for the liver recipient, experienced graft rejection, meaning that their immune system attacked the transplanted organ.[125]

Documents produced to the Committee show that CADN had serious concerns about the blood type assignment during the organ transplant process. For example, on December 21, 2020, a representative from CADN called UNOS for help, asking "at what point do we feel comfortable with [the results of a blood typing test] from a hospital when we know [the donor has been transfused with over 30 units of type O blood]."[126] CADN noted that the donor's "red cells are identifying as O however the serum is identifying as B"[127] and stated that CADN can "[get his blood] tested further, but it'll take two days and he is ready for allocation now."[128] UNOS advised CADN "to [put] something in donor highlights, big and bold, so everyone sees it . . . and notify primary [transplant] centers," and that "you should be okay."[129] CADN asked the UNOS representative if they had experienced a case like this before.[130] The UNOS representative stated, "this is a fairly new situation for me."[131]

It's important to note here that this is <u>not</u> a new situation within UNOS. In fact, UNOS updated its ABO policy as recently as June 2020, months before this incident, adding "indeterminate" testing (the policy violation at issue in this case) to the UNOS policy guidelines.[132] (In an interview with Senator Grassley and Senator Wyden's staff, Chris Curran,

[121] UNOS_7_000029172.
[122] UNOS_7_000029172, at 29173.
[123] UNOS_4_00033024.
[124] UNOS_4_00033024.
[125] For the liver recipient, the transplant center plasmapheresed the transplant recipient in advance so that their body would accept the ABO B liver. This process filters the blood, removes harmful antibodies, and allows the recipient to receive a donation from a donor of a different blood type. *See* UNOS_4_000330241, at 330243.
[126] UNOS_4_000330241, at 330300.
[127] UNOS_4_000330241, at 330300.
[128] UNOS_4_000330241, at 330301.
[129] UNOS_4_000330241, at 330301-02.
[130] UNOS_4_000330241, at 330302.
[131] UNOS_4_000330241, at 330302.
[132] *Notice of implemented actions*, OPTN, https://optn.transplant.hrsa.gov/policies-bylaws/notices-of-implemented-actions/ (lasted reviewed July 22, 2022).

former-Chair of UNOS's Operations & Safety Committee, highlighted the emphasis UNOS places on addressing blood typing issues.)

In its post-case review, UNOS noted that CADN should have conducted additional and more specific genetic blood testing in this case.[133] In fact, internal memoranda show that Stanford Health Care transplant center asked CADN to delay the procurement due to the discrepancy in ABO typing and requested additional testing. CADN denied the request, pointing to a variety of factors including "confidence in the ABO," lack of ICU bed space, and the fact that other centers had accepted other organs.[134] According to UNOS's internal staff summary, on December 22, 2020: [135]

- Hours before the donor OR, **CASU**, who had accepted the heart, expressed concerns about donor ABO accuracy and requested a 48-72 hour delay for additional ABO testing. **CADN** declined the request due to confidence in the ABO, two accepting centers with blood bank expert consults, lack of available ICU space, and donor family concerns for length of case. **CASU** declined the heart, which **CASD** subsequently accepted.

Following the transplant, CADN self-reported the incident to UNOS, noting that CADN staff incorrectly assigned ABO O to a donor who had undergone a massive blood transfusion.[136] On December 31, 2020, UNOS sent an inquiry letter to CADN about the event.[137] In response to the UNOS inquiry letter, CADN staff describe the "gaps" in policy that contributed to this error over emails to UNOS staff.[138] One gap identified was that, when CADN staff became aware of the inconclusive results, they did not escalate the issue to clinical leadership, as their "interim instructional" guidance stated. [139] The email follows:[140]

[133] UNOS_4_000330241, at 330317.
[134] UNOS_4_000330241, at 330245.
[135] UNOS_4_000330241, at 330245.
[136] UNOS_4_000330241.
[137] UNOS_4_000330241, at 330264.
[138] UNOS_6_000096902, at 96903.
[139] UNOS_ 4_000330241, at 330261; UNOS_6_000096902, at 969006.
[140] UNOS_6_000096902, at 96903.

Hi [redacted]

Upon review of our process, we see a few possible gaps:

- 2.1.4.2.1. says "All available typing and subtyping results must be assessed and found to be equivalent (e.g. hospital results, first laboratory result, second laboratory result)". We think we may not have recognized cancelled tests as a "result", and in general not considered all results.
- 2.1.4.6.2 indicates resolving discrepancy by testing at donor hospital "or" other designated testing site. This conflicts with the following bullet that indicates using the guidelines, which indicate testing at hospital and an outside lab.
- 2.2.2.2 indicates a huddle if discrepancies cannot be resolved

The interim instructional statement says:

- "All ABO tests must be considered when determining a donor's blood type. If any test indicates anything other than a conclusive result (including cancellation), or is in any way inconsistent with other ABO testing; all results must be reviewed by organ program clinical leadership and must follow SE-M-001, Section 2.2, Guidelines for Handling Conflicting Primary Blood Type Results. This includes testing by an outside (non-hospital) lab"

We believe this statement emphasizes the need to consider all results as stated in 2.1.4.2.1; it addresses 2.1.4.6.2 by requiring a result from an outside lab, and it indicates a huddle much earlier in the process (when conflicting results are identified).

The impact of this ABO typing error was nearly fatal for three of the four organ recipients. For example, the heart transplant recipient received extracorporeal membrane oxygenation post-transplant.[141] This is a life sustaining treatment where "blood is pumped outside of your body to a heart-lung machine that removes carbon dioxide and sends oxygen-filled blood back to tissues in the body," requiring intensive care unit monitoring.[142] The kidney recipients both required removal of the transplanted organs to avoid further complications.[143]

According to UNOS's internal staff summary, it appears that one reviewer recommended a finding of non-conformance while also sending the case to the full MPSC board "as it resulted in graft loss for multiple patients."[144] A second reviewer recommended UNOS issue CADN a "notice of non-compliance at minimum" because of "clear communication and disclosure of ABO discrepancies with accepting transplant centers."[145] A third reviewer also recommended a notice of non-compliance at a minimum and referral to the full MPSC. The Committee did not receive information from UNOS on the final disposition of this case.

[141] UNOS_ 4_000330241, at 330252.
[142] *Extracorporeal membrane oxygenation (ECMO)*, MAYO CLINIC (Apr. 19, 2022), https://www.mayoclinic.org/tests-procedures/ecmo/about/.
[143] UNOS_ 4_000330241, at 330315.
[144] UNOS_ 4_000330241, at 330242.
[145] UNOS_ 4_000330241, at 330242.

APPENDIX B
We Are Sharing Hope (SCOP)
Re: ABO Blood Type Mix Up

On November 28, 2018, We Are Sharing Hope (SCOP), the organ procurement organization (OPO) serving South Carolina, reported a blood typing incident that impacted multiple transplant recipients. For some transplant recipients, the event was fatal. Between November 27 and 28, 2018, three of the four accepting transplant hospitals experienced patient safety events related to this blood typing error and reported the events to UNOS.[146] This case was made public in 2020, when the patient's family filed a lawsuit against SCOP.[147] On November 28, 2018, after receiving the safety incidents, UNOS notified the Health Resources and Services Administration (HRSA), in accordance with Wakefield criteria, which include any issue that may pose a serious threat to patient safety.[148]

Prior to the organ retrieval, the donor received a massive blood transfusion. A massive blood transfusion is a type of blood transfusion given to patients who require a rapid and large replacement of their blood volume, and is often required after a traumatic event.[149] Blood transfusions are one of several clinical situations that result in unreliable blood typing results, as the transfusion antibodies can mix with the patient's antibodies and temporarily cause inconsistent blood typing results, making these donors potentially high risk.[150] However, if the donor's blood type is tested before the transfusion, this problem can be avoided. In this incident, the donor's initial blood type test drawn pre-transfusion had "hemolyzed," meaning the blood cells had ruptured to the point of being unreadable, and were therefore unusable.[151] Therefore, the OPO had to rely on blood typing tests obtained after multiple blood transfusions. The summary of the incident follows:[152]

[146] UNOS_2_000014076, at 14078-84.
[147] Mary Katherine Wildeman, *He died when he got the wrong lungs. It wasn't the only organ error in SC that day*, THE POSE AND COURIER (Sep. 11, 2020), https://www.postandcourier.com/health/he-died-when-he-got-the-wrong-lungs-it-wasnt-the-only-organ-error-in/article_c6a6e386-e704-11ea-91ce-2783df6c6f2d.html.
[148] UNOS_3_000088965. The Wakefield criteria is a set of patient safety criteria, developed by HRSA to help UNOS determine what cases must be escalated to HRSA, the Membership and Professional Standards Committee (MPSC), and UNOS leadership as well as how quickly a case needs to be escalated.
[149] *UpToDate*, https://www.uptodate.com/contents/massive-blood-transfusion (last visited July 19, 2022).
[150] *Organ Procurement & Transplantation Network*, https://optn.transplant.hrsa.gov/professionals/by-topic/guidance/guidance-for-addressing-blood-type-determination/ (last visited July 19, 2022).
[151] UNOS_2_000014075, 14154.
[152] UNOS_2_000014075.

OPO 02412N allocated the lungs, heart, liver, pancreas, left kidney, and right kidney from a donor who had undergone massive transfusion with ABO O blood products. The OPO subsequently determined that the donor was ABO O. Testing later revealed that the donor was actually ABO A1.

Hospital 41473N received the heart and transplanted it into an ABO B recipient. After release of crossclamp, the heart stiffened and became edematous. Hospital 41473N was unable to get the recipient off of CPB, and converted to VA ECMO. After six days the heart recipient was re-transplanted. The heart recipient is doing well and was discharged home 22 days after the second transplant.

Hospital 46029N received the liver and transplanted it into an ABO O recipient. The recipient is doing well and is not expected to have an adverse course related to the incompatible ABO.

Before SCOP allocated the organs, it obtained a series of inconclusive blood typing samples. The initial ABO sample showed an indeterminate result. However, "the donor hospital also does not report indeterminate results per internal policy, so the OPO was not aware of the initial indeterminate result."[153] A second ABO was drawn and sent to an outside lab for testing. This sample was also found to be indeterminate.[154] SCOP later admitted that had they "known that the first ABO typing was also indeterminate in addition to the second typing at the serology lab, this would have been a 'red flag.'"[155] Instead, SCOP drew a third sample, which had a similar result as the second sample. SCOP "considered this ABO as confirmation of the first ABO and a resolution of the discrepant ABO typing found at the outside lab."[156]

SCOP staff then notified the Administrator on Call (AOC) and the Clinical Donation Coordinator (CDC) of the results. However, "given that there were two ABOs drawn at the donor hospital on different dates with the same results the AOC did not notify the Medical Director of the 'indeterminate' results."[157] SCOP staff then notified the transplant centers that the donor was "hemodiluted and therefore PHS Increased Risk."[158] "Given that there were two ABOs drawn at the donor hospital on different dates with the same results the CAT did not notify the transplant programs of the indeterminate ABO result."[159] On November 28, 2018, one day after procurement, the transplant hospital who accepted the donor's pancreas notified SCOP that a (now fourth) sample they had tested resulted as ABO A. The OPO alerted the other transplant centers, but the other organs had already been transplanted.[160]

[153] UNOS_2_000014075, at 14076.
[154] UNOS_2_000014075, at 14076.
[155] UNOS_2_000014075, at 14076.
[156] UNOS_2_000014075, at 14076.
[157] UNOS_2_000014075, at 14076.
[158] UNOS_2_000014075, at 14076.
[159] UNOS_2_000014075, at 14076.
[160] UNOS_2_000014075, at 14089.

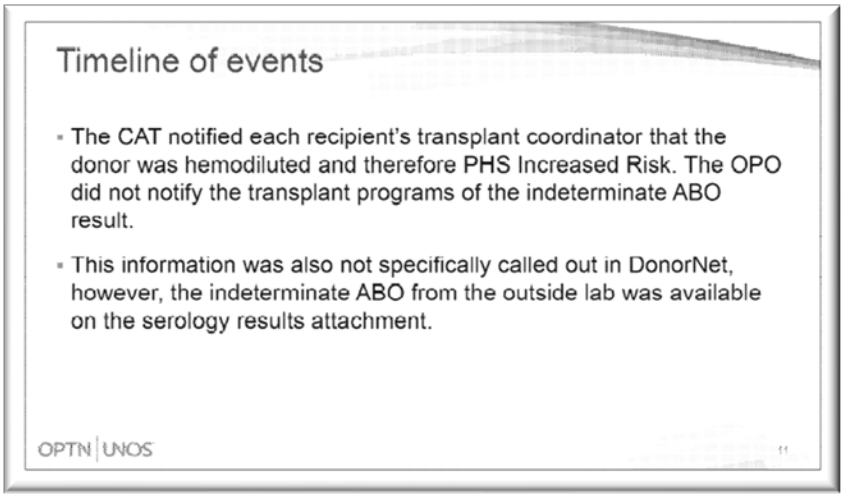
On December 10, 2018, UNOS staff sent an inquiry letter to SCOP requesting additional information about the case and, on December 24, 2018, SCOP sent their response.[161] Over the coming weeks, UNOS staff sent multiple inquiries and received multiple responses from SCOP that ultimately resulted in the Membership and Professional Standards Committee's (MPSC) request for an informal discussion with SCOP.[162] In its request, the MPSC expressed multiple concerns with what it had discovered up to this point:[163]

MPSC Concerns

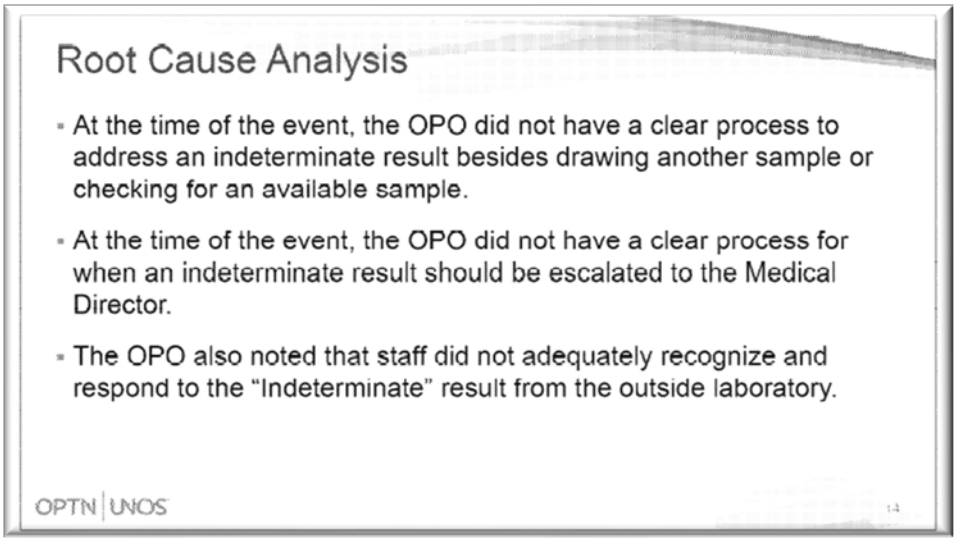
The MPSC leadership was concerned by the failure of SCOP's staff and AOC to recognize the potential safety consequences of indeterminate blood typing issues. The group was concerned with the use of broad terminology such as mass transfusion and indeterminate blood type instead of firm clinical and situational triggers when determining which donor cases go for AOC and Medical Director review. Finally, the group was particularly concerned that SCOP did not accept responsibility for this event and look internally to assess what OPO staff could have done to prevent this event, regardless of the actions of the donor hospital.

In a MPSC presentation dated February 26-27, 2019, the MPSC Compliance Operations Analyst discussed this case.[164] After reviewing the timeline of events, the MPSC discovered that, although the blood typing results from the outside lab was made available to transplant centers in an attachment, the information was not explicitly stated on DonorNet and not clearly relayed. DonorNet is the UNOS platform that, "match[es] each unique organ to the best-suited candidates, and send[s] automated organ offers to transplant surgeons for acceptance or refusal."[165] The timeline of events follows:[166]

[161] UNOS_2_000014075, at 14076.
[162] UNOS_2_000015134.
[163] UNOS_2_000015134-15135.
[164] UNOS_2_000015338.
[165] *Technology for transplants*, UNOS, https://unos.org/technology/technology-for-transplantation/ (last reviewed July 22, 2022).
[166] UNOS_2_000015338, at 15349.



Additionally, the root cause analysis (RCA) found a variety of contributing factors at SCOP:[167]



SCOP took multiple corrective actions to address the error, including an immediate containment plan to prevent this from happening again and the developed of a "hard stop" playbook to trigger the containment plan.[168]

On February 27, 2019, the MPSC met and reviewed all of SCOP's documentation as well as the subcommittee's recommendations.[169] On March 19, 2019, the MPSC issued a "Notice of Noncompliance to SCOP for failure to follow policy 2.6.A 'Deceased Donor Blood Type

[167] UNOS_2_000015338, at 15351.
[168] UNOS_2_000015338, at 15352.
[169] UNOS_6_000067181.

Determination.'" Ultimately, this case resulted in the death of the lung recipient, near-death of the heart recipient, and two kidney discards.[170]

This was not the first incident of a blood typing error gone wrong at SCOP. In 2003, a teenager died after a blood typing error related to a heart and lung transplant.[171] Furthermore, in the MPSC presentation, dated February 26-27, 2019, the Compliance Operations Analyst discussed another ABO case gone wrong at a different OPO, happening only two months prior to the SCOP event.[172] As a result of these incidents, the OPTN Operations and Safety Committee (OSC), revised the OPTN policy at issue. (The OSC's mission it to, "identify potential improvements and policy revisions that may prevent future such occurrences."[173]) In September 2020, OSC modified the OPTN guidance and policy to address blood type determination, adding "indeterminate" to the conflicting results criteria.

[170] UNOS_2_000015338, at 15350.
[171] Mary Katherine Wildeman, *He died when he got the wrong lungs. It wasn't the only organ error in SC that day*, THE POSE AND COURIER (Sep. 11, 2020), https://www.postandcourier.com/health/he-died-when-he-got-the-wrong-lungs-it-wasnt-the-only-organ-error-in/article_c6a6e386-e704-11ea-91ce-2783df6c6f2d.html.
[172] UNOS_2_000015338, at 15375.
[173] *Organ Procurement and Transplantation Network*, https://optn.transplant.hrsa.gov/policies-bylaws/notices-of-implemented-actions/ (last visited July 19, 2022).

APPENDIX C
Life Connection of Ohio (OHLC)
Re: Cancer Transmission Case

On March 29, 2020 at 04:25AM EST, Life Connection of Ohio (OHLC), an organ procurement organization (OPO) serving northwest Ohio, received an organ donation referral from St. Luke's Hospital for a patient diagnosed with intracerebral hemorrhage, or bleeding into the brain.[174] OHLC conducted a medical record review of the patient on March 29, 2020 at 9:20 a.m.[175] The patient's condition continued to deteriorate and, on March 31, 2020, OHLC began an organ match run against donor waiting lists.[176] Several organs were matched, including the donor's heart.[177]

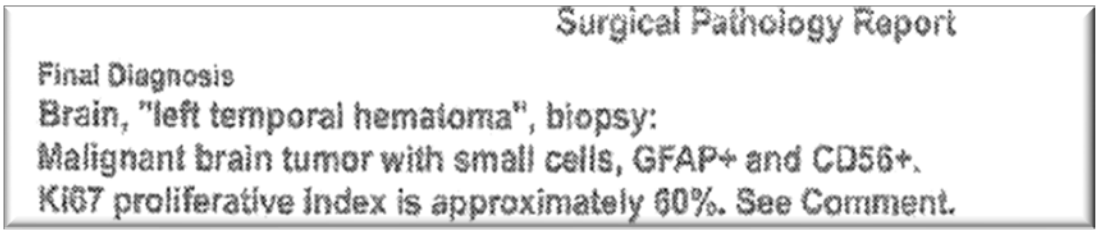
The patient was determined to be brain dead by her attending physician on April 1, 2020 at 9:31 p.m. and OHLC was called for organ recovery.[178] OHLC recovered multiple organs between April 1, 2022 and the early morning of April 2, 2020.[179]

On March 30, 2020, one day after OHLC conducted their medical record review of the patient, but two days before brain death, organ match runs, and organ recovery, the donor hospital received a surgical pathology report from a brain biopsy of the donor.[180] Stated in the report was the preoperative diagnosis with a note:[181]


Clinical Information
Procedure: CRANIOTOMY.
Preoperative diagnosis: HEAD PAIN, RULE OUT BRAIN TUMOR.

The surgical pathology report was signed April 1, 2020 at 10:23 a.m., 11 hours before donor brain death and subsequent organ recover, and notes the final diagnosis as "[m]alignant brain tumor with small cells." [182]

[174] UNOS_3_000046430, at 46431.
[175] UNOS_3_000046430, at 46431.
[176] UNOS_3_000046430, at 46431.
[177] UNOS_3_000046430, at 46432.
[178] UNOS_3_000046430, at 46437.
[179] UNOS_3_000046430, at 46431.
[180] UNOS_3_000046430, at 46431.
[181] UNOS_3_000046430, at 46439.
[182] UNOS_3_000046430, at 46439.



Surgical Pathology Report

Final Diagnosis
Brain, "left temporal hematoma", biopsy:
Malignant brain tumor with small cells, GFAP+ and CD56+.
Ki67 proliferative index is approximately 60%. See Comment.

On April 22, 2020, OHLC discovered that a brain biopsy occurred prior to organ recovery.[183] After learning about the cancerous biopsy results, OHLC notified each transplant center that accepted organs from the donor and submitted a "Potential Disease Transmission Report" to UNOS.[184]

OHLC also reached out to Community Tissue Services, an organ and tissue bank, to inquire about the incident, writing:

> "this was just forwarded to me. Do you know why this was performed? Was there suspicion?"[185]

Community Tissue Services replied:

> "There was mention of malignant brain tumor in the hospital chart and the slides were sent to UM for further evaluation. We just followed up to make sure the further evaluation did not reveal anything of concern."[186]

On June 4, 2020, UNOS received a complaint about OHLC from a transplant recipient who received a heart transplant from a donor who died of cancer.[187] The complaint alleges OHLC failed to identify the donor's cause of death due to metastatic glioblastoma and that the transplant recipient was informed they "may likely die within 3 years" due to the donor's malignancy.[188] The patient's complaint followed that his transplant doctor told him "he doesn't know how [the OPO] 'messed up' and did not catch this prior to [transplant]."[189]

UNOS opened a review on June 22, 2020.[190] In response to UNOS's inquiry, OHLC stated that their medical record review, which occurred days before recovery, found "no documentation of malignancy" or mention that specimens were sent to pathology prior to organ recovery.[191] OHLC also stated that the discharge note did not include a mention of a brain malignancy.[192] In addition to evidence a donor brain tumor was received by the donor hospital in the days between OHLC's medical record review and the donor's brain death and organ

[183] UNOS_3_000046430, at 46431.
[184] UNOS_3_000046430, at 46431.
[185] UNOS_3_000046430, 46438
[186] UNOS_3_000046430, 46438
[187] UNOS_3_000046449.
[188] UNOS_3_000046451.
[189] UNOS_3_000046451.
[190] UNOS_3_000086246.
[191] UNOS_3_000046430, at 46431.
[192] UNOS_3_000046430, at 46431.

donation, records available at the time of OHLC's initial review also contain indicia of a brain tumor. Medical records produced to the Committee show that documentation was available to OHLC from a head CT performed on March 28, 2020 which states that an "underlying mass or infarct not entirely excluded," meaning that the radiologist could not rule out a brain mass.[193]

OHLC responded on July 7, 2020 with responses to UNOS's questions concerning the sequence of events and procedures followed.[194] In addition to providing clinical information, OHLC noted they updated their policies to prevent these events by requiring the Patient Transplant Coordinator to review all pathology reports during the initial donor evaluation as well as prior to going to the operating room for recovery.[195] On July 31, 2020, UNOS informed OHLC that they were not requesting additional information and would not forward this case to the MPSC.[196]

[193] UNOS_3_000046430, at 46431.
[194] UNOS_3_000046430.
[195] UNOS_3_000046430, at 46433.
[196] UNOS_3_000046456.

APPENDIX D
LifeQuest Organ Recovery Services (FLUF)
Re: Cancer Transmission Case

On February 18, 2018, FLUF recovered a liver and heart for transplant.[197] According to FLUF, "[o]rgan recovery was unremarkable."[198] However, documentation available to FLUF prior to organ procurement indicated otherwise stating, "redness/irritation noted between the legs/scrotal area with scrotum having notable swelling."[199] On February 19, 2018, an autopsy further noted, "numerous hemorrhagic nodules were noted on the right testicle."[200] Pathology later found testicular embryonal carcinoma.[201] The root cause analysis reported to UNOS's Disease Transmission Advisory Committee (DTAC) stated: [202]

2.19.18 0918 EST	The pathologist in the District Two Leon County Medical Examiner's office performed the autopsy on 2/19/18 at 0918 EST. According to the autopsy report, during the autopsy, "numerous hemorrhagic nodules were noted on the right testicle." Pathology later revealed right testicular embryonal carcinoma, and this was included in the final autopsy report. Also included, was a statement in all capital letters: "EVIDENCE OF MEDICAL INTERVENTION AND ORGAN PROCUREMENT". There were several other statements regarding organ recovery throughout the report.

Despite the notation: "EVIDENCE OF MEDICAL INTERNVENTION AND ORGAN PROCUREMENT," the organ procurement organization (OPO) did not receive the results of the autopsy until approximately June 11, 2018, more than 4 months after the autopsy.[203] LifeQuest's Medical Director reviewed the autopsy report, dated, initialed, and submitted it to the quality assurance (QA) staff to be scanned into the donor record.[204] However, the Medical Director did not note that the donor had testicular cancer.[205]

According to FLUF, on February 15, 2019, FLUF's "Director of Clinical Operations received a call from a Mayo Clinic transplant coordinator, who stated that during the liver transplant recipient's one-year follow up appointment, an ultrasound revealed a large liver mass and was confirmed by MRI."[206] In addition, "[b]iopsy of the mass indicated that it was a germ cell tumor, probably embryonal."[207]

[197] UNOS_2_000010576, at 10577.
[198] UNOS_2_000010576, at 10580.
[199] UNOS_2_000010576, at 10597.
[200] UNOS_2_000010576, at 10580.
[201] UNOS_2_000010576, at 10580.
[202] *Ad Hoc Disease Transmission Advisory Committee*, OPTN, https://optn.transplant.hrsa.gov/about/committees/ad-hoc-disease-transmission-advisory-committee/ (last reviewed July 21, 2022); *see also* UNOS_2_000010576, 10580.
[203] UNOS_2_000010576, at 10580.
[204] UNOS_2_000010576, at 10580.
[205] UNOS_2_000010576, at 10580.
[206] UNOS_2_000010576, at 10580.
[207] UNOS_2_000010576, at 10580.

2.15.19 0900	On the morning of February 15, **2019**, the Director of Clinical Operations received a call from a Mayo Clinic transplant coordinator, who stated that during the liver transplant recipient's one-year follow up appointment, an ultrasound revealed a large liver mass and was confirmed by MRI. Biopsy of the mass indicated that it was a germ cell tumor probably embryonal. It was asked by the Mayo coordinator if we would review our donor record to determine if this could have been donor derived.
2.15.19 0930	The Director of Clinical Operations quickly began reading through the donor record and eventually found the autopsy report from the ME office that revealed testicular embryonal carcinoma. She immediately notified the Associate Executive Director who then notified the Executive Director.

2

Following this call, FLUF's Director of Clinical Operations found the autopsy report that revealed testicular embryonal carcinoma.[208] In a call to Duke later that morning, FLUF was told the heart recipient died of multi-system organ failure in November 2018, although that patient did not demonstrate evidence of cancer, and was also told that "treatment would begin" for the liver recipient.[209] The case was entered into the UNOS's patient safety portal later that same day.[210]

2.15.19 1000-1300	Between the hours of 1000-1300 Mayo (liver), Duke (heart) and DTAC were notified of the finding. During the call to Duke, the transplant coordinator stated that the heart patient died of multi-system organ failure in November of 2018, and never demonstrated any evidence of cancer. The Mayo liver surgeon indicated that treatment would begin for the recipient and that they reported this possible disease transmission to DTAC.
2.15.19 1605 EST	The Executive Director called the Medical Director to inform him.

Nine days later, on February 28, 2019, UNOS notified FLUF that it would look into the report and asked questions concerning the incident.[211] FLUF responded on the same day.[212] On March 7, 2019, UNOS notified FLUF of an MPSC review into the case.[213] In documents produced to UNOS in response to that inquiry, FLUF reported that "[t]he LifeQuest medical director overlooked this critical finding when he originally viewed the Medical Examiner's autopsy report on June 11, 2018. This is the reason why the autopsy findings were not communicated to Mayo nor UNOS/DTAC."[214]

Ultimately, MPSC issued a "Notice of Noncompliance" for policy Violation 15.4 (Host OPO Requirements for Reporting Post-Procurement Test).[215] UNOS's remedial action was not public.

[208] UNOS_2_000010576, at 10581.
[209] UNOS_2_000010576, at 10580-10581.
[210] UNOS_2_000010569.
[211] UNOS_2_000010650.
[212] UNOS_2_000010576, at 10577.
[213] UNOS_2_000010610.
[214] UNOS_2_000010612.
[215] On file with the Committee.

APPENDIX E
Nevada Donor Network (NVLV)
Re: Kidney Death Case and Testing Failures

On July 13, 2017, a kidney transplant recipient died six days post-transplant from a rare bacterial infection.[216] When the Centers for Disease Control (CDC) learned about this incident on July 19, 2017, they contacted UNOS for additional information about this "public health emergency."[217] UNOS knew of the incident 5 days prior, but did not share any information with the CDC until the CDC reached out to UNOS. Furthermore, UNOS staff did not have any knowledge of the event because, it appears, the UNOS safety analyst who received the initial incident report did not escalated it to UNOS leadership, the Health Resources and Services Administration (HRSA), or the CDC when UNOS was first alerted about the patient death.[218]

On July 14, 2017, the Nevada Donor Network (NVLV), an organ procurement organization (OPO) in Nevada, self-reported through UNOS's patient safety portal information about two transplant recipients who had developed serious complications shortly after transplant, leading to the death of one recipient.[219] In its submission, NVLV stated that, a "report from NVUM revealed [the patient] deteriorated post-transplant and ultimately expired on 7/13/17."[220] The UNOS safety analyst who received this case labeled it a "low" priority.[221]

The recipients had contracted a rare infection known as tularemia.[222] Tularemia is "a rare infectious disease caused by the bacterium Francisella tularensis."[223] The infection "attacks the skin, eyes, lymph nodes and lungs," and is "also known as rabbit fever or deer fly fever," as it primarily affects rodents such a squirrels, rabbits and hares.[224]

On July 17, 2017, UNOS staff reached out to NVLV to confirm receipt.[225] The notification follows:[226]

[216] UNOS_1_000042009.
[217] UNOS_6_000015441, at 15442-43.
[218] UNOS_1_000042009, at 42010.
[219] UNOS_1_000042009. UNOS_6_000015447 at 15449.
[220] UNOS_1_000042009.
[221] UNOS_1_000042009, at 42010.
[222] UNOS_6_000015447, at 15449.
[223] *Tularemia*, MAYO CLINIC, https://www.mayoclinic.org/diseases-conditions/tularemia/ (last updated Nov. 6, 2020).
[224] *Tularemia*, MAYO CLINIC, https://www.mayoclinic.org/diseases-conditions/tularemia/ (last updated Nov. 6, 2020).
[225] UNOS_1_000042015.
[226] UNOS_1_000042015.

UNOS' Member Quality Department received your correspondence through the UNet℠ Patient Safety Portal concerning a deceased kidney recipient. Specifically, you have raised concerns that the kidney recipient died 6 days post-transplant, and that both kidney recipients had a similar post-transplant course of illness. At this time, investigation into possible disease transmission, contamination, or other causes of the death are pending.

Two days later, on the morning of July 19, 2017, CDC received notification about the event from state public health labs and began communicating with HRSA and UNOS.[227] CDC expressed their serious concerns to UNOS writing: [228]

Sent from my iPhone
On Jul 19, 2017, at 2:50 PM, [redacted]@cdc.gov> wrote:

Dear all,
We just received a call from our bacterial diseases group at CDC as they were notified of two patients (in CA and NV) who have confirmed tularemia infection – both were recipients of kidneys from a common donor. One (NV) recipient has died.

Have you (UNOS) received a report on this? CDC obviously will accept the investigation. We do not know yet if there are other organ recipients or tissues were recovered.

Please let us know as soon as you hear back about this
I am available at all times at below contact information

[redacted]

[redacted]
Office of Blood, Organ, and Other Tissue Safety
Division of Healthcare Quality Promotion
Centers for Disease Control and Prevention

The email continues:[229]

Sent from my iPhone
On Jul 19, 2017, at 2:57 PM, [redacted]cdc.gov> wrote:

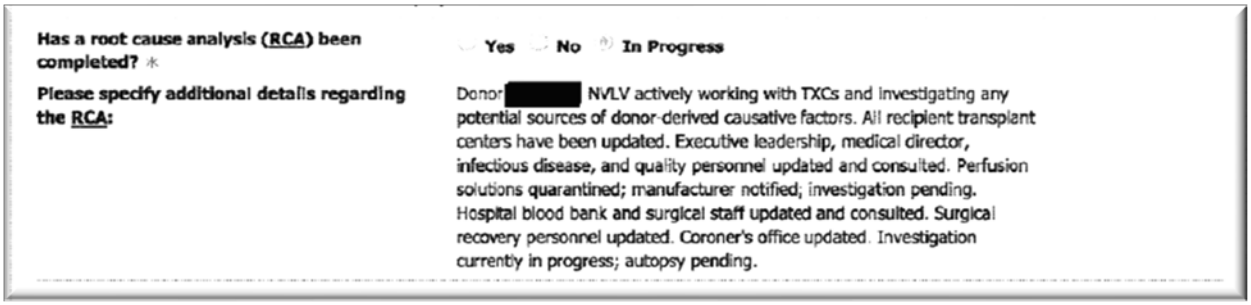
Just to clarify—our CDC contact did not know which OPO or which transplant centers were involved.

She was notified by the state public health labs and had otherwise scant information.

This is obviously a public health emergency so we wanted to get to work on this immediately as there may be dozens of healthcare workers at risk in addition to organ/tissue recipients.

[227] UNOS_6_000015447, at 15443 and 15449.
[228] UNOS_6_000015441, at 15443.
[229] UNOS_6_000015441, at 15442.

CDC requested information from UNOS about what transplant centers were aware of the event and for all recipient and transplant center information.[230] UNOS staff told the CDC that they were made aware of the event by the transplant center for the "left kidney recipient," but did not mention NVLV's self-report submitted five days prior.[231] Additionally, UNOS staff did not appear to be aware of the fact that NVLV had already alerted all of the transplant centers about the potential risk, which would have been valuable information for the CDC:[232]



Has a root cause analysis (RCA) been completed? *	Yes No In Progress
Please specify additional details regarding the RCA:	Donor [redacted] NVLV actively working with TXCs and investigating any potential sources of donor-derived causative factors. All recipient transplant centers have been updated. Executive leadership, medical director, infectious disease, and quality personnel updated and consulted. Perfusion solutions quarantined; manufacturer notified; investigation pending. Hospital blood bank and surgical staff updated and consulted. Surgical recovery personnel updated. Coroner's office updated. Investigation currently in progress; autopsy pending.

Additionally, it does not appear that the complaint received on July 14, 2020 was escalated through to UNOS leadership, which is required under OPTN policy as a threat to public health or patient safety.[233] Ultimately, the outcome of this case is unclear based on the documents reviewed by the Committee.

[230] UNOS_6_000015441-42.
[231] UNOS_6_000015441.
[232] UNOS_1_000042009.
[233] *See, e.g.*, UNOS_3_000039007, at 39010. Staff were unable to locate an intake form from this event.

APPENDIX F
Mississippi Organ Recovery Agency (MSOP)
Re: Late Kidney

On February 27, 2017, the transplant center at Mayo Clinic Hospital in Arizona, reported 2 instances within 3 ½ months where kidneys were delayed in transit, resulted in extended cold ischemic time (CIT) on 2 kidneys and the discard of a third kidney.[234]

The first incident occurred on December 17, 2016 and the second occurred on February 25, 2017.[235] According to the report submitted by the Mayo Clinic to UNOS's patient safety portal:[236]

> AZMC [or, Mayo Clinic Hospital in Arizona] is reporting two instances where NGL (Network Global Logistics) was used as the transportation courier service and the organs did not arrive to the airport in time to make the flight. This resulted in 3 cancelled kidney transplants due to prolonged cold ischemic time.

On March 27, 2017, UNOS reached out to MSOP to inquire about the incident:[237]

> We are currently reviewing a kidney allocation by Mississippi Organ Recovery Agency for donor [Redacted]. Our preliminary analysis indicates that a courier was unable to deliver the kidney to the airport in time to make the scheduled flight. The kidney was ultimately discarded.

Despite UNOS requesting further information from the organ procurement organization (OPO) and reportedly receiving a response,[238] the case was closed with no apparent action. In UNOS's closure letter, UNOS indicated that the MPSC would not review the case, even though it resulted in a discarded organ.[239]

It is interesting to note that, unless a complaint is submitted under the "donor" section of UNOS's patient safety portal, the complainant does not have the option to indicate the case resulted in a discard. In this case, the discard was only noted in the complaint's text.[240] This indicates that UNOS's systems may not be able to track these types of incidents.

[234] UNOS_3_000076146-47.
[235] UNOS_3_000076146-47.
[236] UNOS_3_000076146-47.
[237] UNOS_3_000076155-57.
[238] The response was not provided to the Committee.
[239] UNOS_3_000076166.
[240] UNOS_3_000076146.

APPENDIX G
Donor Alliance (CORS)
Re: Kidney Courier Case (Transportation Failure/Organ Discarded)

On April 21, 2018, Donor Alliance, the organ procurement organization (OPO) serving Colorado and most of Wyoming, filed a patient safety event report regarding Sterling Courier services and UNOS.[241] The report stated that, due to a data entry error, Sterling Courier left the right kidney at CORS because their paperwork only instructed them to pick up the left kidney.[242] The report also stated that communication failures at the UNOS Organ Center, the division of UNOS that assists in supporting organ transportation, and the intended recipient's transplant center regarding alternate transportation resulted in extended delays.[243] The description of the event as reported in the patient safety portal is as follows:

> A kidney for transplant was left at the Donor Alliance Recovery Center by Sterling Courier. According to their paperwork, they were to only pick up the left kidney. There was a data entry error by Sterling Courier that led to the right kidney not being added to the job with the left kidney. There was additional miscommunication between UNOS and NYRT on acceptance of the right kidney and arranging transport of the right kidney. Donor Alliance was never made aware that the right kidney was not picked up with the left kidney. DA was also not notified when alternate arrangements were supposed to be made by UNOS for right kidney to NYRT UNOS did not have proper handoff between shifts and to DA. The consequence of the errors in communication is that a transplantable organ had to be discarded and a recipient who was expecting to receive that kidney was not going to get a transplant.[244]

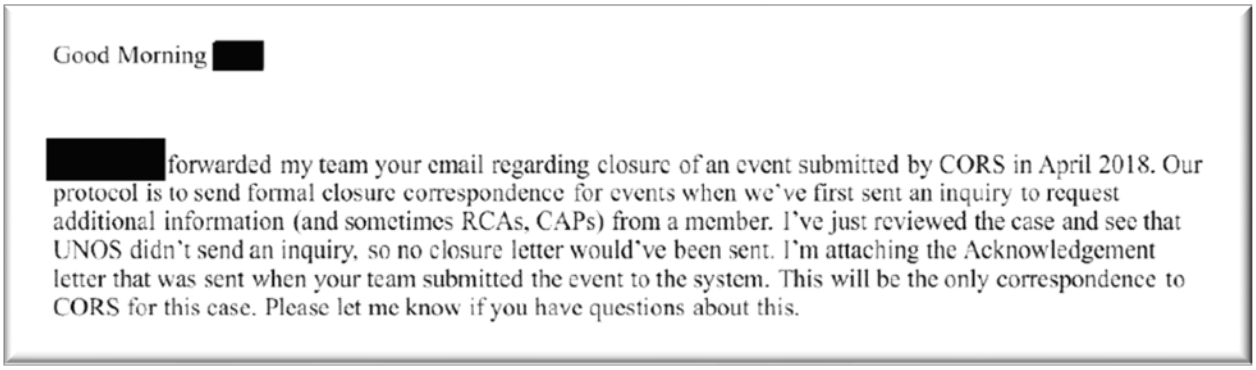
Following this event, Sterling Courier, UNOS, and CORS each conducted a root cause analysis (RCA) of the event.[245] It appears these entities completed their RCAs before Donor Alliance submitted the report to UNOS, as all three RCAs were included with the report that was entered into the patient safety portal one month following the event.[246]

UNOS's RCA found there was "lack of clear or complete communication during hand off from one shift to the next."[247] UNOS recommended corrective actions and announced a pilot a program that would list active transportation as "active cases" on their dashboard to eliminate gaps during shift changes.[248] Sterling's RCA found that their internal shipment tracking system, QuickTrak, did not save the job due to a customer service representative not hitting the right key upon exiting.[249] Lastly, CORS's RCA found that their organ staff did not communicate with tissue staff regarding courier pick up.[250] As a

[241] UNOS_3_000039007.
[242] UNOS_3_000039003, at 39004.
[243] UNOS_3_000039003, at 39011.
[244] UNOS_3_000039003-05.
[245] UNOS_3_000039003, at 39005.
[246] UNOS_3_000039003, at 39005.
[247] UNOS_3_000039003, at 39005.
[248] UNOS_3_000039003, at 39005.
[249] UNOS_3_000039003, at 39005.
[250] UNOS_3_000039003, at 39005.

corrective action, CORS staff planned, "to implement a communication process (white board and log for communication between organ and tissue teams.")[251]

On July 12, 2021, CORS staff reached out to UNOS requesting documentation that the matter was closed, as they did not have anything in their records.[252] UNOS responded to CORS, explaining: [253]



Good Morning [redacted]

[redacted] forwarded my team your email regarding closure of an event submitted by CORS in April 2018. Our protocol is to send formal closure correspondence for events when we've first sent an inquiry to request additional information (and sometimes RCAs, CAPs) from a member. I've just reviewed the case and see that UNOS didn't send an inquiry, so no closure letter would've been sent. I'm attaching the Acknowledgement letter that was sent when your team submitted the event to the system. This will be the only correspondence to CORS for this case. Please let me know if you have questions about this.

This email correspondence seems to suggest that UNOS never conducted additional inquiries or an investigation into this matter. Ultimately, the right kidney was discarded as these errors in communication lead to increased cold ischemic time that left the kidney non-viable.[254] There was no MPSC outcome for this complaint, as it never became a UNOS patient safety case, which demonstrates UNOS's lack of effort to address transportation errors and enforce best practices among its members.

[251] UNOS_3_000039003, at 39005.
[252] UNOS_6_000022475.
[253] UNOS_6_000106060.
[254] UNOS_3_000039007-11.

APPENDIX H
We Are Sharing Hope (SCOP)
Re: Airline Case 1

On September 25, 2015, Jackson Memorial Hospital Transplant Center in Miami (FLJM) reported a patient safety event via UNOS's patient safety portal (PSP).[255] FLJM identified errors transporting a kidney which ultimately resulted in the organ being discarded.[256] The intake form notes that a right kidney was accepted from We Are Sharing Hope (SCOP), a South Carolina based organ procurement organization (OPO), for transport and was "misplaced by American Airlines."[257] When it was found at 7:00 a.m., the transplant team declined the kidney because extended cold ischemic time (CIT) rendered it unusable.[258] CIT is the time from when an organ has no blood flow and is cooled down for transportation to the time it is warmed up again for transplant and blood flow is restored.[259] On the PSP submission, SCOP notes that they completed a root cause analysis (RCA) and found that a "non-standard airline [was] used due to flight availability."[260] The September 25, 2015, patient safety submission follows:[261]

> Right kidney accepted for transplant at FLJM from SCOP. Organ sent by SCOP using courier NGO and American Airlines. Organ misplaced by American Airlines and transplant cancelled. Per [redacted] (OPO coordinartor: [redacted] organ found @ 0700 and sent make to OPO for discard. Cold time making organ usage impossible.

At their weekly meeting on September 30, 2015, UNOS staff reviewed this case. As a next step, UNOS decided to "reach out to SCOP to ensure that there is no responsibility on behalf of the OPO and this was truly an airline issue. If so, can close as done with previous cases." [262] A week later, on October 6, 2015, UNOS requested information from SCOP about the case and, on October 14, 2015, SCOP responded to UNOS, citing the change in airline carriers by their courier service as the source of the problem. The email follows:[263]

> Here is a time line of the transportation issues that we had with the right kidney on [redacted] We use Network Global Logistics (NGL) for out of state courier services. NGL normally uses Delta Airlines as primary and United Airlines as secondary on all jobs. On this particular day, Delta's systems were down and could not accept shipments. United did not have a flight that arrived in Miami before the American Airlines flight. Therefore, we used American for this shipment.

[255] UNOS_3_000086989-90.
[256] UNOS_3_000086985.
[257] UNOS_3_000086985.
[258] UNOS_3_000086985.
[259] *Cold ischemia time*, NATIONAL CANCER INSTITUTE https://www.cancer.gov/publications/dictionaries/cancer-terms/def/cold-ischemia-time (last reviewed July 22, 2022).
[260] UNOS_3_000086989, at 86990.
[261] UNOS_3_000086990.
[262] UNOS_5_000034100.
[263] UNOS_3_000086992.

SCOP further noted that, due to the change in airline services, the courier service was not aware that the new airline did not automatically place a "lifeguard" status on organs and therefore did not request it.[264] The OPO admits, "had they done this, it is unlikely that the package would have been lost as easily." [265] SCOP also explained that the kidney was:[266]

> located on a luggage trolley in the ramp area. [redacted] told me that American Airlines does not automatically place a "lifeguard" status on organ shipments like Delta and United do. Since NGL doesn't routinely use American for these shipments, his CSR's did not think to request this urgent status for this shipment. Had they done this, it is unlikely that the package would have been lost as easily. NGL will be reviewing their policies and training their CSRs to always request lifeguard status on shipments of organs.

On October 21, 2015, UNOS again discussed this case again at their weekly meeting:[267]

> Email confirmed that SCOP's courier used a different airline than normal, American versus Delta. American had accidently left the kidney on a luggage tug and by the time it was found, there was too much CIT for reallocation. Reviewed again with group and group in agreement to close.

UNOS closed this case never sent it to the Membership and Professional Standards Committee (MPSC). As noted above, the kidney was discarded due to the extended CIT, which rendered it non-viable. This was one of three transportation errors at SCOP between 2015 and 2017.[268]

[264] UNOS_3_000086992, at 86993.
[265] UNOS_3_000086992, at 86993.
[266] UNOS_3_000086992, at 86993.
[267] UNOS_5_000034100.
[268] UNOS_6_000007958.

APPENDIX I
We Are Sharing Hope (SCOP)
Re: Airline Case 2

On March 29, 2017, UNOS sent an inquiry letter to We Are Sharing Hope (SCOP), the organ procurement organization (OPO) for South Carolina, to request information about a potential allocation error.[269] Earlier that month, on March 2, 2017, two kidneys had missed their flight.[270] However, SCOP was able to re-route the organs to a local transplant center at the last minute and another candidate received the organs. In its March 29, 2017 letter, UNOS states:[271]

> We are currently reviewing a matter of a kidney allocation from We Are Sharing Hope SC for donor [redacted]. Our preliminary analysis indicates that both kidneys were allocated to the center at sequence #1; after two flights were missed, the kidneys had to be re-allocated to a local center.

UNOS also asks about potential violations of their allocation policy, questions "[w]hy the kidneys were unable to be placed on the scheduled flights," and requests that SCOP provide any root cause analysis (RCA) completed or corrective action plans (CAP) implemented.[272] On April 12, 2020, SCOP responded that their courier service, MNX Global Logistics (MNX), had completed a RCA and explained that the carrier's failure to load the kidney in time for the departure flight was the cause of the delay. SCOP's response follows:[273]

> The incident was reviewed by MNX Courier in conjunction with Delta Airlines. MNX indicated that the root cause was failure of Delta Airlines to load the right kidney on the originally booked flight and subsequent flight to LAX.

As a corrective action, the airline planned to brief their ramp personnel and management on the issue:[274]

> **MNX root cause-** Failure of Delta Airlines to load the right kidney on the originally booked flight and subsequent flight to LAX.
>
> **Corrective Action:** MNX has reviewed this with Delta Management and they are aware of the severity of this incident and will brief their ramp personnel/ramp management.

[269] UNOS_3_000088813.
[270] UNOS_3_000088813.
[271] UNOS_3_000088813.
[272] UNOS_3_000088813.
[273] UNOS_3_000088815, at 88816.
[274] UNOS_3_000088815, at 88822.

However, Committee staff believe that the airline was not the only cause of the delay. For example, on March 2, 2017, at 8:28 p.m., the courier service called the OPO to let them know that the kidney was not on the intended flight because "someone mistakenly put tomorrow's date for fly out."[275] SCOP staff contacted the receiving center to let them know that the kidney would miss its original flight due to this error. SCOP reported the following timeline of events:[276]

03/02/2017	20:28	CAT received a call from [redacted] CSR with MNX, who advised that the kidney outbound for Cedars-Sinai was not placed on the intended flight (Delta 1218) and then someone mistakenly put tomorrow's date for fly out. Kidney should now fly out on Delta flight 1128 and arrive at LAX at 0008 PST with delivery by 0200. She said her manager [redacted] is involved as is upper management trying to resolve this. They will give me an update later. CAT notified Legacy One (OPO) at 2035 and spoke to [redacted] a coordinator, explained what had happened with the kidney missing the flight, advised of new anticipated delivery time, and answered her questions. The CAT then updated AOC at 2049.

That same night, the courier service again notified SCOP that, despite receiving the GPS coordinates, Delta Airlines was unable to locate the organ in time for the second scheduled flight. The courier service offered to charter the kidney, to which the clinical allocation coordinator (CAT) at the OPO responded, "almost certainly not and requested next available commercial flight to LAX tomorrow morning."[277] It is unclear why the CAT did not take the courier service up on their offer when a chartered flight would have gotten the kidney to its intended location on time.

SCOP then decided that the "best plan is to try get [the] kidney back to Charleston presuming [the transplant center] declines for cold time."[278] The receiving center again reached out to SCOP, this time asking if there was an earlier flight. Despite SCOP's offer to move the kidney onto an earlier American Airlines flight, the transplant center ultimately declined due to the prolonged cold ischemic time (CIT), or the time from which an organ has no blood flow and is cooled down for transportation to when it is warmed up for transplant and blood flow is restored.

During its weekly case review meeting held on April 18, 2017, UNOS staff identified the airline carrier as the cause of the event and reported: "Delta failed to load kidney on first flight, then, despite being given GPS coordinates, was unable to find it to load onto second flight."[279] UNOS staff "agreed to close" this case during the meeting.[280] UNOS also wrote to SCOP, stating that it did not require additional information and would not forward the case to the Membership and Professional Standards Committee (MPSC).[281] Therefore, the MPSC did not review this

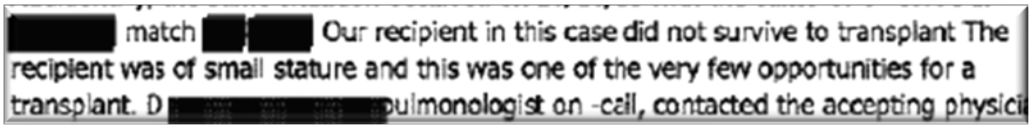
[275] UNOS_3_000088815, at 88820.
[276] UNOS_3_000088815, at 88820.
[277] UNOS_3_000088815, at 88821.
[278] UNOS_3_000088815, at 88821.
[279] UNOS_5_000034100.
[280] UNOS_5_000034100.
[281] UNOS_3_000088831.

case. Although this organ was transplanted at a local transplant center, the original recipient missed their opportunity for a life-saving transplant. This was one of three transportation errors at SCOP between 2015 and 2017.[282]

[282] UNOS_6_000007958.

APPENDIX J
LifeGift Organ Donation Center (TXGC)
Re: Allocation Error Case

On February 7, 2019, UNOS received a complaint that LifeGift Organ Donation Center (TXGC), an organ procurement organization (OPO) in Houston, Texas, improperly allocated a heart and lungs recovered from a donor.[283] The reporting hospital stated that this was the second occurrence of this issue with the OPO. The hospital also noted that their waitlisted patient, who they believed should have received the organs as a matter of OPTN policy, did not survive to transplant.[284]


[redacted] match [redacted] Our recipient in this case did not survive to transplant The recipient was of small stature and this was one of the very few opportunities for a transplant. D[redacted]pulmonologist on -call, contacted the accepting physici

The report described two separate cases, one dated October 2018 and the other February 2019, where TXGC offered the donor's lungs separate from the heart. In the first instance, the lungs were matched before the heart was offered to the waiting list.[285] In the second instance, the OPO received a provisional acceptance for the heart first, and then matched the lungs while the heart offer was still provisional.[286] The provisional heart match was then declined.[287]

In both instances, the heart was eventually matched with the reporting hospital whose patient needed both a heart and lungs.[288] In both instances, the hospital that matched with the heart requested that TXGC rescind the lung offer so both could be allocated to their patient, per OPTN Policy 6.5.F Allocation of Heart-Lungs:[289]

> **Relevant OPTN Policies:**
> **6.5.F Allocation of Heart-Lungs:** "When a heart-lung candidate is allocated a heart, the lung from the same deceased donor must be allocated to the heart-lung candidate." (Policy in effect prior to October 18, 2018)

TXGC refused this request, believing that, because the lungs had already been matched, rescinding the offer would itself be a violation of OPTN policy.[290] The October 2018 case does not appear to have been immediately submitted to UNOS for assistance resolving the disagreement.[291] In the February 2019 case, not only did the same disagreement between the

[283] UNOS_4_000281833, at 281835.
[284] UNOS_4_000281833, at 281835.
[285] UNOS_4_000281833-34.
[286] UNOS_4_000281833-34.
[287] UNOS_4_000281833-34.
[288] UNOS_4_000281833-34.
[289] UNOS_4_000281833-34.
[290] UNOS_4_000281833-34.
[291] UNOS_4_000281833-34.

same entities result in the death of a waitlisted patient who died before transplant, the repeat dispute caused "unnecessary delays" and the recovered heart was discarded without being transplanted.[292]

After receiving a report of both incidents, UNOS sent a letter to TXGC on February 13, 2019[293] and, on February 20, 2019, TXGC sent their follow up response.[294] TXGC stated that neither a root cause analysis nor a post case review had been performed and provided corrective actions including that "placement staff will enter code 898 and specify that the center refused when a center refuses to provide or confirm decline codes," in effect placing blame entirely on the transplant hospital for the incident.[295]

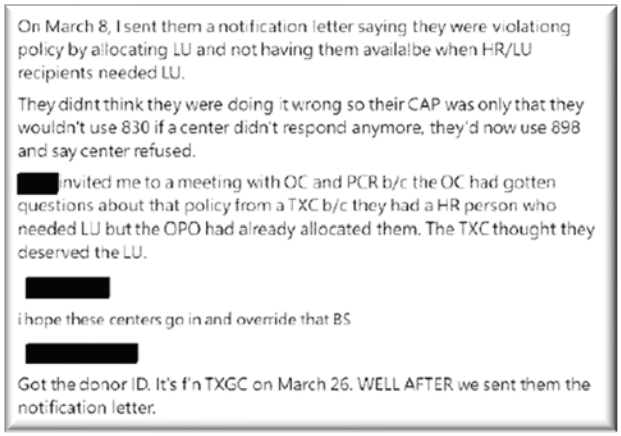
On February 25, 2019, UNOS staff wrote to a colleague questioning TXGC's decision to delay allocation and asked for guidance on their response to TXGC:[296]

From: [redacted]unos.org>
Sent: Monday, February 25, 2019 1:40 PM
To: [redacted]unos.org>
Subject: Additional Questions to TXGC

Will you review this before I send to TXGC? Essentially, I can't verify any of the information they gave me on one of the donors because there are no PYs or Acceptance in DonorNet. They also "blame" FLTG for their inability to place the heart b/c of "unnecessary delays"...b/c they waited 6 hours before they finally skipped over FLTG, even though a back-up center only has 30 minutes to accept/decline when they're notified they're primary, or the OPO can move right on to the next one. So, #4 I'm having the hardest time with. They don't HAVE to move along to the next one after 30 minutes, but they can. And even though they CAN move along after 30 minutes, their response specifically says they stopped waiting after six hours AND it was this "unnecessary delay" on behalf of FLTG that led to the inability to place this heart. They're blaming FLTG for taking too long ...but they didn't need to wait that long. So while it's not a policy violation to wait 6 hours, I want to know why they did...and if this delay and the lack of PYs and Acceptance on this match run can be indicative of a larger issue with this allocation in general (i.e., was this a hot mess from the start?).

After UNOS notified TXGC that it had potentially committed a policy violation, TXGC once again allocated organs in a way that violated the same OPTN policy. According to internal UNOS staff correspondence:[297]

[292] UNOS_4_000281833-34.
[293] UNOS_4_000281833, at 281837-39.
[294] UNOS_4_000281833, at 281837-39 and 281843.
[295] UNOS_4_000281833 at 281845; UNOS_4_000281432.
[296] UNOS_6_000011277.
[297] UNOS_6_000010682.


On March 8, I sent them a notification letter saying they were violationg policy by allocating LU and not having them availalbe when HR/LU recipients needed LU.

They didnt think they were doing it wrong so their CAP was only that they wouldn't use 830 if a center didn't respond anymore, they'd now use 898 and say center refused.

[redacted] invited me to a meeting with OC and PCR b/c the OC had gotten questions about that policy from a TXC b/c they had a HR person who needed LU but the OPO had already allocated them. The TXC thought they deserved the LU.

[redacted]

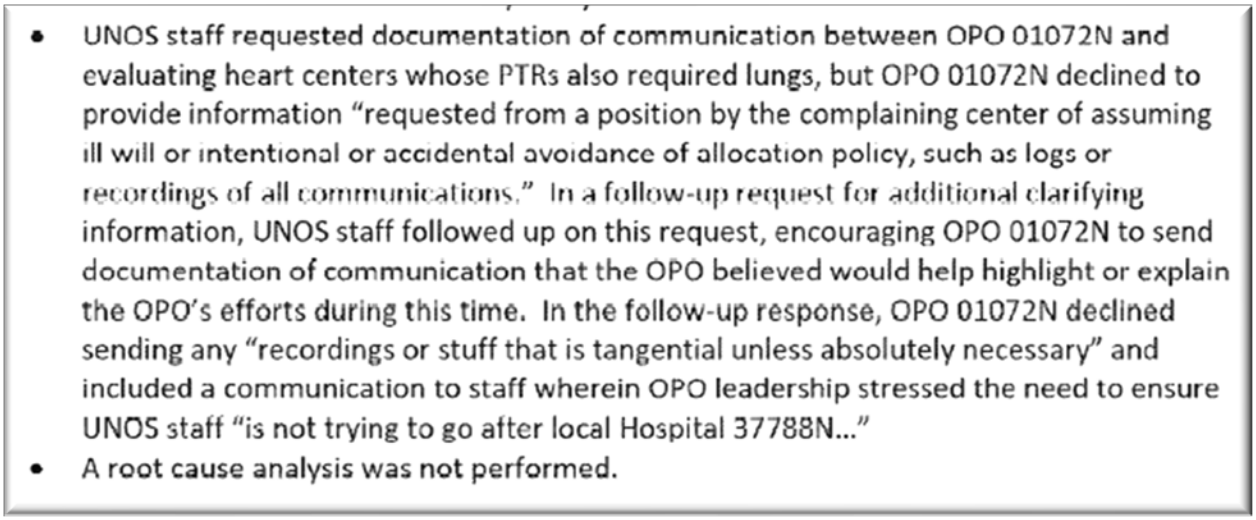
i hope these centers go in and override that BS

[redacted]

Got the donor ID. It's f'n TXGC on March 26. WELL AFTER we sent them the notification letter.

On May 2, 2019, UNOS staff discussed UNOS's reluctance to look into the case further. They stated that senior UNOS staff were "reluctant" to take the case because the "OC [Organ Center]" does not refer every "potential violation" and that it would be unfair if UNOS staff investigated this case further since UNOS does not investigate all similar cases.[298] Another staffer responded: "unless the issue represent (sic) a threat to patient safety or to the fairness of allocation, I don't think we need to see all of it."[299] This implies UNOS staff do not consider all cases resulting in the death of transplant recipient or when an organ is discarded, as threats to patient safety. UNOS did not pursue the third case.[300]

In addition to UNOS not investigating the case, TXGC also resisted efforts by UNOS to investigate the matter. According to summary materials prepared by UNOS:[301]


- UNOS staff requested documentation of communication between OPO 01072N and evaluating heart centers whose PTRs also required lungs, but OPO 01072N declined to provide information "requested from a position by the complaining center of assuming ill will or intentional or accidental avoidance of allocation policy, such as logs or recordings of all communications." In a follow-up request for additional clarifying information, UNOS staff followed up on this request, encouraging OPO 01072N to send documentation of communication that the OPO believed would help highlight or explain the OPO's efforts during this time. In the follow-up response, OPO 01072N declined sending any "recordings or stuff that is tangential unless absolutely necessary" and included a communication to staff wherein OPO leadership stressed the need to ensure UNOS staff "is not trying to go after local Hospital 37788N..."
- A root cause analysis was not performed.

Despite TXGC's efforts, the case was eventually referred to the Membership and Professional Standards Committee (MPSC) to review its corrective action plan and determine if

[298] UNOS_6_000010639.
[299] UNOS_6_000010639.
[300] UNOS_6_00009979, at 10003.
[301] UNOS_4_000281432.

any policy violations occurred. In advance of the MPSC's review, UNOS staff created a "Staff Summary" and noted that cases such as these typically result in a "Notice of Noncompliance." [302]

> **Historical MPSC actions:** The MPSC would typically issue a Notice of Noncompliance in cases involving allocation policy violations. The MPSC has considered higher actions (Letter of Warning, etc.) if the member has a significant compliance history, if the nature of the violation poses a significant patient safety risk, if the member did not adequately correct the root cause of the violation, etc.

In addition to this recommendation, the staff summary prepared by UNOS also contained initial review by three MPSC members. Two agreed with issuing a "Notice of Noncompliance," except one, Alex Glaizer, a close confidant of UNOS CEO Brian Shepard, who recommended closing with no action. [303]

> **Reviewer Comments:**
>
> **Reviewer 1:** I agree with Notice of Noncompliance for Policies 6.5.F and 6.6.F.i.
>
> **Reviewer 2:** I am not clear why this is a policy violation at all? The sequence of allocation appears to be that the OPO appropriately allocated lungs and then later in the allocation process the ctr with a heart candidate needing lungs requested the OPO rescind the prior lung offer? This seems like an inappropriate request by the ctr. Will that behavior be addressed by the MPSC? My question for the OPO is, in these circumstances where heart allocation has to resume after lungs have been placed, why is the OPO offering a heart to a candidate listed as needing heart/lungs? If the lungs are no longer available, those candidates should be screened off to avoid this type of frustrating circumstance. I think this case should be closed with no action and I think there should be correspondence back to the Ctr about making requests for OPOs to rescind offers.
>
> **Reviewer 3:** Agree with notice of noncompliance for applicable policies.

Despite these recommendations, at a July 2019 MPSC meeting, reviewers voted to close the case with no action.[304]

During the July MPSC meeting, UNOS staff responsible for handling the TXGC matter discussed the case with a coworker over a digital chat.[305] She wrote, "I'm pissed though," to which her colleague responds, "I know, but lots of OPO peeps in here. strong opinions." The UNOS staff replies, "No joke. Poor outnumbered thoracic peeps. Policy clearly says "must." There are hardly any policies that say "must." The staffer then follows up noting to their colleague that, in a similar instance, the OPO admitted they had been wrong to allocate the lungs out of order from the heart:[306]

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[302] UNOS_4_000281432-33.
[303] UNOS_4_000281432-33; UNOS_7_000001938.
[304] UNOS_2_000000019, at 28.
[305] UNOS_6_000009977-78.
[306] UNOS_6_000009977-78.

Well they're getting one from NYRT, who admits that their staff's decision to let the LU stay primary b/c they'd been waiting for 12 hours was wrong b/c they know that HR/LU people get the LU.

They admit that they should hold LU until HR is placed.

On the same day, this UNOS staffer simultaneously discussed the TXGC case over digital chat with a second UNOS staffer. The conversation follows:[307]

[redacted]

if history is any indication, this will be a close or a NON b/c TXGC is impenetrable

The colleague responded:

so

uh

still no problem??

they really just want to focus on the superficials of the case

[redacted]

sure, look at their volume...but also look at their history.

[redacted]

and not probe I guess

[redacted]

YES [308]

After some back and forth, this UNOS staff wrote their colleague again saying: [309]

[307] UNOS_6_00009979, at 10000.
[308] UNOS_6_00009979, at 10001.
[309] UNOS_6_00009979, at 10003.



[310]

It is important to note that UNOS has not issued guidance on how OPTN members should interpret this policy in relation to multi-organ transplant candidates. This lack of clarity was also not addressed in recent policy changes intended to clarify multi-organ allocation policy approved by the OPTN Board in June 2021.[311]

[310] UNOS_6_00009979, at 10003.
[311] *Notice of OPTN Policy Changes, Clarify Multi-Organ Allocation Policy*, OPTN (2021), https://optn.transplant.hrsa.gov/media/4698/clarify_multi-organ_june_2021_policy_notice.pdf.

APPENDIX K
Indiana Donor Network (INOP)
Re: DCD Case

On February 24, 2017, UNOS received an anonymous tip from a caller who said, "[t]hat he had heard things that had been weighing on him and he wanted to ensure that UNOS knew and looked into it."[312] The caller reported the following concerns to UNOS:[313]

Concerns:

- Donor was alive when he was opened to recover organs.
- Support was withdrawn in the OR and the team monitored the HR for 5 minutes.
- Donor was opened.
- After the donor was opened, a heartbeat was identified. Heart rate was again monitored, and ten minutes later the donor died.
- Sources have told the reporter that the recovering surgeon was the physician who declared death, then proceeded with organ recovery.
- The attending may have been in the room the whole time, but reporter says he is privy to information that says otherwise and that the recovering surgeon declared the patient dead.
- He wants to ensure that we review the DCD vitals in the attachments and take note of times.

On the same day, at 3:06 p.m., the UNOS safety analyst proceeded to fill out the Member Quality Intake Form, checking "no" for the question that states, "[w]as there direct and specific harm to an identified patient or patients?"[314] The analyst also marked this as a "medium" case, which required the Assistant Director or Director to notify the Executive Director within three days of intake.[315] Three days later, on February 27, 2017, the same safety analyst wrote to their superior and colleagues asking, "[w]ill there be time to discuss my INOP case at today's huddle or right after? I found some stuff in DonorNet, and I'm not convinced this should be a medium case."[316]

UNOS closed this case and never referred it to the MPSC. However, based on documents reviewed by the Committee, it is unclear what transpired after this email exchange. UNOS noted, "all appropriate documentation provided by OPO. No policy violations identified," although it is unclear what, if any, communication, or follow up, UNOS had with INOP regarding this case.[317]

Failing to submit cases generated by anonymous complaints to the MPSC is part of a broader trend identified by the Committee. Senate staff found that anonymous complaints were referred to the MPSC only 27% of the time.[318] Whereas complaints submitted by an Organ Procurement and Transplantation Network (OPTN) member were referred to the MPSC 62% of the time.[319]

[312] UNOS_3_000007163.
[313] UNOS_3_000007163.
[314] UNOS_3_000007164.
[315] UNOS_3_000007164, at 7166.
[316] UNOS_6_000016228.
[317] On file with the Committee.
[318] On file with the Committee.
[319] On file with the Committee.

Additionally, at the time of this event, INOP was under scrutiny by both UNOS and the Centers for Medicare and Medicaid Services (CMS) regarding brain death declaration and documentation. For example, on September 23, 2016, CMS wrote a letter to INOP stating the OPO was "out of compliance" finding, "deficiencies so serious they constitute an immediate threat to patient health and safety."[320] The letter stemmed from INOP's failure to verify and document pronouncement of the donor's death in accordance with local, state, and federal laws (and OPO policy) in three cases.[321]

INOP was also undergoing a corrective action plan to address issues identified in a UNOS Member Quality Review.[322] The audit from this site survey covered cases from July 1, 2014 to July 1, 2016, and found donor records without documentation verifying death in accordance with applicable laws.[323] A few months later, on October 4, 2016, UNOS site surveyors issued a report documenting six donor records with irregularities in brain death pronouncement documentation and testing.[324] INOP was ultimately placed on probation in November 2016, and was serving that probation at the time this incident was reported to UNOS.[325]

Based on documents identified by the Committee, it appears UNOS did not notify CMS about this complaint, despite their concern with INOP's, "deficiencies so serious they constitute an immediate threat to patient health and safety."[326]Additionally, as noted above, this complaint was never referred to the MPSC for further review.

[320] UNOS_3_000001436.
[321] UNOS_3_000001436, at 1440.
[322] UNOS_3_000001147.
[323] UNOS_3_000002608.
[324] UNOS_3_000002605.
[325] UNOS_3_000004004.
[326] UNOS_3_000001436.

APPENDIX L
Life Alliance Recovery Organization (FLMP)
Re: DCD Case

According to a complaint received by UNOS, on November 28, 2018, Life Alliance Recovery Organization (FLMP), an organ procurement organization (OPO) based in Miami, Florida, recovered organs from a donor before the donor's heart stopped and against the family's wishes.[327] The UNOS summary of the case follows:[328]

> **Staff Summary:** An individual called to report this event to UNOS Member Quality staff. A brain dead patient was authorized as a DCD donor because the family wanted to be in the OR when the heart stopped. Despite this, the OPO began recovery prior to cardiac asystole after communicating to staff that the case was not a DCD case because the patient had already been declared brain dead. As a corrective action, the OPO stated it would no longer recover brain dead patients as DCD donors. If a family did not authorize brain dead recovery, the OPO would shut down the case.

On November 19, 2018, a 41-year-old donor was admitted to the hospital after a motor vehicle accident and was declared brain dead on November 24, 2018.[329] The family decided to proceed with donation, but only after cardiac death (DCD).[330] However, when it came time to recover the organs, the family changed their mind regarding DCD donation.[331] Despite this, "the OPO began recovery prior to cardiac asystole after communicating to staff that the case was not a DCD case because the patient had already been declared brain dead."[332] The MPSC staff summary further states:[333]

> After extubation, the mother "became traumatized, changed her mind about witnessing cardiac standstill and left the OR and instructed the OPO to proceed with organ recovery."
> The OPO chose to recover organs based on the previous day's brain death declaration, prior to asystole, based on "verbal agreement from the mother and brother."

On July 19, 2019, the Member and Professional Standards Committee (MPSC) began its review of the case and requested an informal discussion with FLMP.[334] The committee noted they were "concerned by the lack of a root cause analysis (RCA) and the decision to no longer permit brain dead patients to be DCD donors."[335] After this informal discussion, which took place on September 25, 2019, the subcommittee remained concerned about the OPO's decision to decline donation in the future if a brain dead patient's family is only willing to authorize a

[327] UNOS_1_000011869, at 11870.
[328] UNOS_1_000023933.
[329] UNOS_1_000011869-70.
[330] UNOS_1_000011869, at 11870.
[331] UNOS_1_000011885.
[332] UNOS_1_000023933.
[333] UNOS_1_000026510, at 26511.
[334] UNOS_1_000023933.
[335] UNOS_1_000023933.

DCD recovery. The subcommittee was also concerned by the OPO's decision to proceed with organ recovery prior to asystole in this case and requested the OPO conduct an RCA. On October 14, 2019, FLMP submitted its responsive RCA to the MPSC.[336] Additionally, as requested, FLMP "consulted with other OPOs regarding their policies and processes for DCD recoveries of brain-dead donors, and created and amended some of its policies and procedures."[337]

On November 7, 2019, the MPSC reviewed FLMP's submission.[338] After its review, the Committee remained concerned "about FLMP's continued assertion that the root cause of this issue was the emotional state of the donor's mother."[339] By proceeding with the type of donation for which FLMP did not have authorization, the MPSC believed FLMP potentially jeopardized the donor family and OR staffs' trust in the donation process and transplant system."[340]

In December 2019, the Centers for Medicare and Medicaid Services (CMS) conducted a complaint survey specifically about this case.[341] Through its survey, CMS reviewed "the case record, interviewed staff and reviewed FLMP's policies. CMS approved FLMP's corrective measures and found the OPO compliant."[342]

On February 26, 2020, during an interview conducted by MPSC, FLMP's Executive Director read a statement reportedly provided by the donor's mother.[343] The statement, written in Spanish and translated by FLMP staff, was intended to demonstrate that the mother wished to proceed with brain death recovery and not DCD recovery.[344] It is unclear when this letter was signed and whether or not the MPSC verified the authenticity of the letter.[345] After its in-person review in February, the MPSC decided to issue FLMP a Letter of Warning, for violation of Policy 2.15.H (Organ Recovery) on March 12, 2020.[346] In its decision, the MSPC expressed deep concerns about the operation and culture of the OPO: [347]

[336] UNOS_1_000023933.
[337] UNOS_ 1_000011885, at 11886.
[338] UNOS_ 1_000011885.
[339] UNOS_ 1_000011885, at 11186.
[340] UNOS_ 1_000011885, at 11186.
[341] UNOS_7_000028921-27.
[342] UNOS_1_000011869, at 11871.
[343] UNOS_1_000011869, at 11870.
[344] UNOS_1_000011869, at 11870.
[345] UNOS_1_000011869.
[346] UNOS_1_000011885, at 11887.

Full MPSC Concerns

"The letter bothered me. It's something he [the OPO director] could have obtained an affidavit from people that were in the OR that said it was clear, the intent was clear from the professionals involved. Approaching the grieving parent for that shows a lack of judgement and I don't understand how he could perceive that this body was asking for that."

"My concerns with this case going in have not been alleviated because at the end of the day…they have only demonstrated now in my years of experience of talking to them…that when told we want you to do x, y, z and produce documentation they will do it but are never ahead of the game. They never come and say we had this problem and here is how we fixed it. There's nothing proactive, it is all reactive and is basically filling in the blanks of what any reasonable person could interpret from our comments, questions, and requests for information. So we may not have an issue of recurrence of this particular event again, which it the traditional definition of risk of recurrence, but we have a likely recurrence there are other huge holes in their process from an operational standpoint and a quality standpoint. The questions I asked lead me to believe they have changed their policy but they really haven't changed their mindset as to how they're approaching this. There aren't going to be policies or protocols to cover every nuance…but at the end of the day the ability to stop and have a constructive thought process about what might work, what might go wrong and then be able to defend that is not there…I do doubt they have any meaningful QAPI process, that their policies prepare their staff to deal with challenges that they have, and that their administrators on call are properly engaged to say okay, this is how we're going to handle this. There were a lot of good questions that were asked here that they just were not able to process…They need to get the strongest message we feel is appropriate that they have serious operational issues relative to their quality and their policies."

"Just go back the last 12 months. This OPO bypassed a transplant center while allocating a kidney, which required them to withdraw an offer; allocated a kidney for an SLK to somebody that wasn't on the SLK list; and now has this. And they actually have the audacity to say this isn't as bad as a ABO error. This is a process problem, and the list is ten years long. I think with where we go, it would be okay – well, it wouldn't be okay – if this was their first time in front of us, I think you could look to say there's a learning opportunity, but I think they probably failed that part of grade school. I know they're turned over leadership and everything, but we're going to be here 12 months from now talking about another event going oh we didn't see this one coming, but it will be the same OPO."

"They have a systemic issue with quality systems. Our peer review teams looked at that, our peer review teams were concerned about it. We felt like they had fixed it, and here we have how many incidents since they've be released as a Member Not in Good Standing…it's the same cycle over and over again…you need to think very carefully about what message you are sending them, because they will be back."

Notwithstanding a year's long MPSC review and corrective action plan, MPSC staff continued to have concerns with FLMP, including its "professional culture and environment, at both the staff and administrative levels, whereby staff is uncomfortable stopping processes to identify errors."[348] As a result, on May 12, 2021, the Health Resources and Services Administration (HRSA) directed the Organ Procurement and Transplantation Network (OPTN) to conduct an additional onsite peer visit to help inform the MPSC and HRSA's determination of an ongoing risk to patient health and public safety.[349]

Despite FLMP's persistent failures and process violations over a ten-year period, which were only reported following HRSA's directed onsite peer visit, the MPSC only issued FLMP a Letter of Warning for this incident. On the other hand, CMS, which also conducted an independent investigation, found FLMP compliant. At this time, FLMP remains a certified OPO.

[348] UNOS_3_000059364.
[350] UNOS_3_000007439, at 7440.

APPENDIX M
Indiana Donor Network (INOP)
Re: Trashed Kidneys

On June 12, 2020, Indiana Donor Network (INOP) self-reported an incident to UNOS stating that two kidneys were accidentally thrown in the trash before being packaged for transportation.[350] INOP reported that an, "immediate debrief and [root cause analysis (RCA)] was performed" following the event and that, "the incident occurred because hospital personnel were not familiar with the donation process and assumed the kidneys were left on the back table to be discarded."[351]

On June 16, 2020, UNOS reached out to INOP to inquire about the incident and, on June 30, 2020, INOP sent their response.[352] On July 8, 2020, UNOS sent a follow up letter to INOP notifying them that they would refer this case to the Membership and Professional Standards Committee (MPSC) for the potential violation of Policy "**2.2 OPO Responsibilities** [emphasis included]" which states, "[t]he host OPO is responsible for *all* of the following . . . 10. Preserving, labeling, packaging, and transporting the organs."[353]

In a staff summary prepared for the MPSC, UNOS recommended two options for the MPSC to take:[354]

> **Historical MPSC Actions:** The MPSC would typically close a self-reported case with no action if the member does not have a history of this noncompliance and addressed the issue through its corrective action plan. While the member self-reported this event, the corrective action plan does not appear to adequately address the issue. The MPSC may consider closing the case or issuing a Notice of Noncompliance.

This first recommendation suggests that UNOS and the MPSC have historically looked favorably upon self-reporting and would, "typically close a case with no action."[355] However, three reviewers raise a series of concerns with INOP's RCA and all supported a "Notice of Noncompliance". [356] Reviewer's comments included concerns with INOP's lack of leadership involvement in the RCA, likelihood of reoccurrence, lack of responsibility, and that, "the [corrective action plan] is insufficient in that this event could happen at any hospital, not just the currently involved hospital."[357]

[350] UNOS_3_000007439, at 7440.
[351] UNOS_3_000007439, at 7440.
[352] UNOS_3_000007448.
[353] UNOS_3_000007460, at 7460-61.
[354] UNOS_2_000011591-92.
[355] UNOS_2_000011591-92.
[356] UNOS_2_000011591-92.
[357] UNOS_2_000011591-92.

On November 10, 2020, the MPSC, issued a "Notice of Noncompliance to INOP for violation of policy 2.2 (OPO Responsibilities)."[358]

Additionally, the MPSC requested an informal discussion with INOP, "in order to offer feedback and process improvement suggestions to the OPO."[359] The informal discussion took place on January 21, 2021 and the MPSC reviewed INOP's updated corrective actions at its meeting on February 24, 2021.[360] Based on this review, the MPSC voted to continue monitoring INOP and recommended that INOP take the following actions:[361]

- Develop a chain of custody for all organs
- Conduct a policy review that takes the OPO's growing volumes into consideration
- Develop internal packaging standard operating procedures to promote consistent packaging and mitigate risk of organ discards

It is unclear what the MPSC's final determination of INOP's ensuing response was, and if this case was escalated to the Health Resources and Services Administration (HRSA) or to the UNOS board at any time during the course of the MPSC investigation.

This case calls into question UNOS' ability to educate the transplant community on core functions that, if not properly addressed, "could happen at any hospital, not just the currently involved hospital," resulting in an error that should never happen.[362] To the Committee's knowledge, UNOS has not provided clear guidance on the need to maintain a chain of custody for organs form procurement through to transplant.

[358] UNOS_3_000003581, at 3582.
[359] UNOS_4_000340932.
[360] UNOS_4_000340932.
[361] UNOS_4_000340932.
[362] UNOS_2_000011591-92.

APPENDIX N
Alabama Organ Center (AOC)[363]
Re: Alleged Money Laundering

On February 4, 2011, the United Network for Organ Sharing (UNOS) received a complaint from a whistleblower about improprieties at Alabama Organ Center (AOC).[364] The whistleblower alleged Executive Director Demosthenes Lalisan was participating in a "money laundering" scheme and other financial improprieties, and that AOC was "violat[ing] their own Standard Operating Procedure" resulting in patient safety issues.[365] The complaint goes on to say that Mr. Lalisan paid himself and others "bonuses" anywhere from $8,000 to $20,000 a month with no rationale or explanation of the benefit.[366] In addition, the complaint alleged that in an effort to recover lost revenue, AOC processed several cases that were not cleared by the quality assurance department.[367]

From: [redacted]
Sent: Friday, February 4, 2011 3:06 PM
To: [redacted]@unos.org>
Subject:

There is a high suspicion of money laundering taking place at the AOC. Many employees have expressed their concern. The clinical CPTC's receive a base salary that compensates them for their office time, and a quarterly bonus based on the number of cases worked. This bonus is distributed on the paycheck of the month following the end of the quarter. There is no explanation of benefit on this or formula used to calculate the amount... it just shows up on each coordinator and administrator's check in amounts anywhere from $8,000 - $20,000. The AOC Administrator, Demosthenes Lalisan, gets the largest portion of this bonus (but does not take ANY call). The amount that he pays himself is extremely elaborate. When a coordinator asks for an explanation for the calculation of this bonus, the explanation of how the payment was determined is refused. Each coordinator gets a post-it note at the end of a quarter with the amount of their bonus hand written. It is included on the following check as a lump sum bonus without explanation of how it is calculated. Over the past year, the Administrator of the Alabama Organ Center has managed to pay $2,000,000 in mortgage payments (on three houses), as well as additional lease payments on several luxury vehicles. There is a huge amount of money being distributed within the organization that is not appropriately accounted for. This needs to be investigated. The AOC transplanted fewer organs last year than they had in over 18 years. They violated their own Standard Operating Procedure by sending over 140 tissue charts to RTI for processing without being reviewed by the quality assurance department. This was done in a desperate attempt to recover lost revenue. I hope that you will recognize the seriousness of what is taking place within the organization, and that the issue will be thoroughly investigated. This money has become "blood money" which is being laundered as a result of the proceeds recovered from individuals with the courage to embrace life, despite overwhelming personal tragedy and death of a loved one.

On February 10, 2010, the whistleblower followed up with additional "detailed information" about the complaint.[368] After receiving the complaint, UNOS staff consulted with the MPSC chair and decided to change a scheduled desk review of the OPO to a full, on site

[363] AOC changed its name in February 2019 to Legacy of Hope. *Alabama Organ Center changes name to Legacy of Hope*, UAB.EDU (Feb. 5, 2019), https://www.uab.edu/news/health/item/10146-alabama-organ-center-changes-name-to-legacy-of-hope.
[364] UNOS_3_000015523.
[365] UNOS_3_000015523.
[366] UNOS_3_000015523.
[367] UNOS_3_000015523.
[368] UNOS_3_000015524. The document referenced, "Complaint.docx" in this email, but Committee staff were unable to locate the attachment in the produced records.

review to investigate the allegations of the complaint.[369] The review was conducted in March 2011.[370]

On May 6, 2011, UNOS's Department of Evaluation and Quality (DEQ) sent a letter to AOC notifying them of their plan to review AOC for broader policy violations identified in the whistleblower allegations, but made no mention of the financial improprieties.[371] UNOS sent the letter to Mr. Lalisan, the subject of the complaint, and an individual whom the Federal Bureau of Investigations (FBI) would later charge with healthcare fraud.[372] According to the letter:[373]

> The UNOS Department of Evaluation and Quality received a complaint regarding the operating procedures of Alabama Organ Center. As a result of this complaint and as follow-up to Alabama Organ Center's routine site survey on January 13-14, 2010, DEQ conducted a special on-site survey on March 23-24, 2011. UNOS staff investigated the allegations in the complaint, which involved donors from 2007 through 2010. The site survey portion of the review focused on donors who occurred on or after February 5, 2010. Donors who occurred prior to February 5, 2010 were not included in the site survey report, but are addressed below.
>
> After a detailed review of the information provided by the site survey, the following potential violations of OPTN Policy have been identified:
>
> - Policy **2.2.4** (former OPTN Policy 2.2.3) Donor Evaluation: "Donor evaluation must be performed or coordinated by the Host OPO…"
> - Policy **5.4.1** Internal Labeling Requirements: "The Host OPO is responsible for ensuring that a secure label identifying the specific contents (e.g., liver, right kidney, heart) is attached to the outer bag or rigid container housing the donor organ…"

Staff could not determine if UNOS conducted additional follow up after May 6, 2011.[374]

On August 30, 2011, UNOS sent a letter to AOC after media reports "outlined the recent termination of two executive leaders at [AOC] as a result of 'improper financial relationships with a vendor.'"[375] UNOS requested information from AOC on when they became aware of the allegations and their plan for interim leadership.[376] AOC responded, noting that they were not aware of the issue until August 10, 2011.[377] According to AOC:

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[369] UNOS_3_000016776.
[370] UNOS_3_000016776.
[371] UNOS_3_000015541.
[372] UNOS_3_000015541.
[373] UNOS_3_000015541.
[374] Committee staff identified this case and related files as one of interest to UNOS during its investigation. Committee staff gave UNOS the opportunity to produce additional material or identify documents from the production that would assist the Committee's review. UNOS declined to do so.
[375] UNOS_3_000015552.
[376] UNOS_3_000015552-53.
[377] UNOS_3_000015554-56.

I was informed of a federal investigation of Mr. Dem Lialison, Director of AOC and Mr. Alan Hicks, Associate Director, AOC on Wednesday August 10, 2011. They were being investigated by the Federal Bureau of Investigation (FBI) for allegedly accepting money from a mortuary and crematory company whom we do business with known as Abanks Funeral Home. This is in connection with the AOC's tissue recovery activity not organ recovery activities. The AOC utilized Abanks for transportation of tissue and gift of body donors from our hospitals and for cremation and embalming services that may be required for the tissue and gift of body donors. Both individuals were interviewed by the FBI. Subsequently, both individuals were interviewed by management and both admitted to accepting improper payments from Abanks. Both employees were terminated and the AOC immediately terminated its relationship with Abanks. Our organization has zero tolerance for activities such as this.

Lialison and Hicks later pled guilty to federal fraud charges.[378]

The Committee was unable to identify what, if any, steps UNOS took to investigate the financial improprieties reported to them in March 2011. Instead, it seems UNOS simply rolled the complaint into a broader ongoing review of the OPO for OPTN policy and procedure violations.

[378] Press Release, Dep't of Justice, Former Alabama Organ Center Associate Director Sentenced For Fraud (June 13, 2020), https://www.justice.gov/archive/usao/aln/News/June%202012/June%2013,%202012%20Former%20Alabama%20Organ.html.

United States Senate
Committee on Finance

EXHIBIT LIST

Hearing On

A System in Need of Repair: Addressing Organizational Failures of the U.S.'s Organ Procurement and Transplantation Network

August 3, 2022

Documents Related to ABO Incompatibility Case 1 (Donor Network West)

A. **1.** UNOS_4_000330241-433 – CADN Case Investigation

2. UNOS_6_000096902-06 – Email re CADN Immediate Action

3. UNOS_6_000096910 – Hyperacute Rejection Case Description

4. UNOS_7_000029172-73 – Emails re HRSA Reportable ABO Event (16)

5. UNOS_E_000026571-73 – Emails re MPSC Request for Additional Information (3)

Documents Related to ABO Incompatibility Case 2 (We Are Sharing Hope)

B. **6.** UNOS_2_000014075-160 – MPSC Summary

7. UNOS_2_000014161-90 – Untitled Staff Summary

8. UNOS_2_000015132-33 – Informal Discussion Summary

9. UNOS_2_000015134-36 – MPSC Informal Discussion Request

10. UNOS_2_000015170-223 – MPSC CAP Update

11. UNOS_2_000015278 – MPSC Outcome

12. UNOS_2_000015300-314 – MPSC Presentation January 28, 2019

13. UNOS_2_000015338-80 – ABO Case Informal Discussion Presentation

14. UNOS_2_000015415-16 – SCOP Informal Discussion Summary and SCOP Accepting Informal Discussion

15. UNOS_2_000015578-631 – SCOP Updated Documentation

16. UNOS_2_000015707-08 – MPSC Resolution Letter

17. UNOS_3_000088960-61 – SCOP ABO Incompatible Tx Communication with SCMU

18. UNOS_3_000088965-66 – HRSA Notification

19. UNOS_3_000088967-69 – Patient Safety Net Portal Submission (1)

20. UNOS_3_000088974-77 – MQ Intake Non-Routine Intake and Triage Form

21. UNOS_3_000088978 – Email re Containment Plan

22. UNOS_3_000088985-87 – Emails between UNOS and HRSA

23. UNOS_3_000089072-80 – Emails re Root Cause Analysis (1)

24. UNOS_6_000067181-82 – Notification of Issue of Noncompliance

25. UNOS_6_000120451 – Emails with Patient Safety Team (2)

26. UNOS_E_000005604 – UNOS Request for Informal Discussion

27. UNOS_E_000020881 – NEOR SCOP Comparison with UNOS Employee Data

28. UNOS_E_000027142 – MPSC Slideshow

Documents Related to Cancer Transmission Case 1 (Life Connection)

C. **29.** UNOS_000046430-48 – Internal Emails at Life Connection

30. UNOS_3_000046449 – Intake Form

31. UNOS_3_000046451-52 – Email Notice to Patient Safety Team

32. UNOS_3_000046456 – UNOS Closure Letter

33. UNOS_3_000086246-49 – Notice of UNOS Inquiry

Documents Related to Cancer Transmission Case 2 (LifeQuest Organ Recovery Services)

D. **34.** UNOS_2_000010025-91 – MPSC Summary

35. UNOS_2_000010558-64 – Not included in RCA

36. UNOS_2_000010569 – Referral to Safety Analyst

37. UNOS_2_000010576-609 – DTAC Late Report Response

38. UNOS_2_000010610-11 – DTAC Late Report Notification

39. UNOS_2_000010612-45 – FLUF Follow Up Information

40. UNOS_2_000010650-51 – DTAC Late Report Inquiry

41. UNOS_4_000284063-64 – Staff Summary

42. UNOS_6_000009263-65 – Emails re DTAC Adjudication (1)

Documents Related to Kidney Death Case (Nevada Donor Network)

E. **43.** UNOS_1_000042009-10 – Patient Safety Net Submission

44. UNOS_1_000042015-16 – UNOS Confirmation of OPTN Submission

45. UNOS_6_000015441-443 – Emails re 2 Kidney Recipients with Tularemia (1)

46. UNOS_6_000015447-449 – Emails re 2 Kidney Recipients with Tularemia (2)

47. UNOS_6_000015454-56 – Emails re 2 Kidney Recipients with Tularemia (3)

Documents Related to Courier Case 1 (Mississippi Organ Recovery Agency)

F. **48.** UNOS_3_000076146-48 – Initial Patient Portal Report

49. UNOS_3_000076149-52 – Intake Form

50. UNOS_3_000076155-57 – UNOS Inquiry Letter

51. UNOS_3_000076166-68 – Closure Letter

52. UNOS_6_000007958 – Senate Inquiry Transportation Issues

Documents Related to Courier Case 2 (Donor Alliance)

G. **53.** UNOS_3_000039003-06 – Patient Safety Net Portal Submission (1)

54. UNOS_3_000039007-11 – Intake Form

55. UNOS_6_000022475-76 – UNOS Emails Re Final Letter (1)

56. UNOS_6_000106060-61 – UNOS Email Stating No Inquiry on this Case

Documents Related to Airline Case 1 (We Are Sharing Hope)

H. **57.** UNOS_3_000086983-84 – Confirmation of OPTN Submission

58. UNOS_3_000086985-88 – Intake Form

59. UNOS_3_000086989-91 – Patient Net Submission

60. UNOS_3_000086992-93 – UNOS Request for Information

61. UNOS_5_000034100 – OPO Case Comments

62. UNOS_6_000007958 – Senate Inquiry Transportation Issues

63. UNOS_6_0000020631 – Internal Emails

Documents Related to Airline Case 2 (We Are Sharing Hope)

I. **64.** UNOS_3_000088813-14 – UNOS Inquiry Letter

65. UNOS_3_000088815-30 – SCOP Response to UNOS and Supporting Documents

66. UNOS_3_000088831-32 – UNOS Response to SCOP

67. UNOS_5_000034100 – OPO Case Comments

68. UNOS_6_000007958 – Senate Inquiry Transportation Issues

Documents Related to Allocation Error Case (LifeGift Organ Donation Center)

J. **69.** UNOS_2_000000019-37 – MPSC Meeting Minutes

70. UNOS_4_000281432-55 – OPO Case Investigations

71. UNOS_4_000281833-54 – MPSC Summary

72. UNOS_6_000009977-78 – Messages re TXGC (1)

73. UNOS_6_000009979-1008 – Messages re TXGC (2)

74. UNOS_6_000010527 – Case Packet Email (1)

75. UNOS_6_000010639-40 – Case Assignment Email

76. UNOS_6_000010679-81 – Messages re TXGC (3)

77. UNOS_6_000010682-86 – Messages re TXGC (4)

78. UNOS_6_000010945 – Case Packet Email (2)

79. UNOS_6_000011142-53 – Messages re TXGC (5

80. UNOS_6_000011204-06 –Messages re TXGC (6)

81. UNOS_6_000011277-78 – Additional Questions to TXGC Email

82. UNOS_000106322-23 – Individual Member Focus Improvement Email

83. UNOS_000118050 – Weekly Meeting Email

84. UNOS_7_000001938 – Messages re TXGC (7)

85. UNOS_E_000020545-46 – HL Examples

Documents Related to Donation after Circulatory Death Case 1 (Indiana Donor Network)

K. **86.** UNOS_3_000001436-46 – CMS Site Survey

87. UNOS_3_000001447-88 – INOP Letter and Corrective Action Plan

88. UNOS_3_000002605-07 – Death Declaration SBAR

89. UNOS_3_000002608-87 – OPO Audit August 2016

90. UNOS_3_000003540-43 – INOP Expedited Review

91. UNOS_3_000003545-54 – INOP Peer Review

92. UNOS_3_000003558-60 – INOP BOD Outcome

93. UNOS_3_000003571 – MPSC Recommendation for Release

94. UNOS_3_000003655-60 – INOP MPSC Interview Summary

95. UNOS_3_000004004-227 – INOP Case Release Packet

96. UNOS_3_000006401-04 – DCD Clinical Pathway Form

97. UNOS_3_000007163 – UNOS Emails Reporting the Complaint

98. UNOS_3_000007164-67 – Intake Form

99. UNOS_3_000073704 – SBAR for the Case

100. UNOS_3_000074107 – Board Compliance Monitoring

101. UNOS_6_000016228 – DonorNet Email

102. UNOS_6_000125944-46 – Emails regarding AOPO Call (1)

103. UNOS_6_000125959-60 – Emails regarding AOPO Call (2)

Documents Related to Donor after Circulatory Death Case 2 (Life Alliance Organ Recovery Agency)

L. **104.** UNOS_1_000011846-50 – Informal Discussion Presentation

105. UNOS_1_000011853-56 – FLMP Informal Discussion Summary

106. UNOS_1_000011869-75 – February 26, 2020 Interview Summary

107. UNOS_1_000011885-89 – March 12, 2020 Letter of Warning

108. UNOS_1_000011967-73 – Peer Visit Request

109. UNOS_1_000012916-19 – Root Cause Analysis

110. UNOS_1_000023933-40 – Staff Summary with Reviewer Comments

111. UNOS_1_000026367-71 – February 28, 2019 FLMP Response to UNOS Inquiry

112. UNOS_1_000026414-16 – February 14, 2019 UNOS Donor Management Inquiry

113. UNOS_1_000026490-509 – March 20, 2019 Donor Letter and Exhibits from FLMP

114. UNOS_1_000026510-579 – MPSC Summary (2)

115. UNOS_2_000005165-89 – MPSC Meeting Minutes

116. UNOS_3_000059364-71 – FLMP Staff Summary Peer Visit

117. UNOS_6_000073311-17 – Correspondence (3)

118. UNOS_7_000000378-85 – April 2021 MPSC FLMP Concerns

119. UNOS_7_000028891-900 – Emails re MPSC Review of Peer Visit and OPO (1)

120. UNOS_7_000028921-27 – CMS Report

Documents Related to Kidney trash Case (Indiana Donor Network)

M. **121.** UNOS_2_000011591-611 – MPSC Summary

122. UNOS_3_000003581-83 – Notice of Noncompliance and Informal Discussion Off

123. UNOS_3_000003592-95 – MPSC Informal Discussion Summary January 21, 2021

124. UNOS_3_000007439-41 – Patient Safety Net Portal Submission

125. UNOS_3_000007442-43 – Incident Handling Triage Form

126. UNOS_3_000007444 – Confirmation of OPTN Submission

127. UNOS_3_000007445-47 – Notice of UNOS Inquiry

128. UNOS_3_000007448-59 – Emails INOP Response

129. UNOS_3_000007460-61 – Notification of Submission to MPSC

130. UNOS_4_000340932-33 – Ongoing Monitoring Staff Summary

Documents Related to Financial Allegations Case (Alabama Organ Center)

N. **131.** UNOS_3_000015523 – OPO Employee Email Report to UNOS

132. UNOS_3_000015524 – Follow Up to OPO Employee Email (1)

133. UNOS_3_000015529-40 – MPSC Summary

134. UNOS_3_000015541-43 – May 6, 2011 UNOS DEQ Notification Letter

135. UNOS_3_000015552-53 – August 30, 2011 Media Inquiry

136. UNOS_3_000015554-56 – September 13, 2011 Media Inquiry Response

137. UNOS_3_000015905-17 – April 8, 2011 On Site Survey Report

138. UNOS_3_000016634-52 – May 6, 2011 Amended Site Report and Closing Letter

139. UNOS_3_000016776-77 – OPO Complaint Summary

140. UNOS_3_000065380 – ALOB Timeframe

Other

O. **141.** No Bates Number Available – SFC Presentation re UNOS Review Process

142. UNOS_2_000003541-68 – DTAC Report

143. No Bates Number Available – USDS Report - Modernizing OPTN January 2021

144. No Bates Number Available – February 10, 2020 UNOS Response to SFC

145. No Bates Number Available – January 31, 2022 SFC IT Security Letter

146. No Bates Number Available – July 11, 2022 McGuireWoods Response to SFC Subpoena

147. No Bates Number Available – March 2, 2022 UNOS Response to SFC IT Security Letter

148. UNOS_6_000026526-29 Kid’s Artwork Emails

149. UNOS_6_000028442-46 Overgrown HOA Emails

Issue Involves: OPO 02412N
Issue Reported by: Hospital 41473N
Issue Reported by: Hospital 46029N
Issue Reported by: Hospital 35577N

Issue: Hospitals 41473N, 46029N, and 35577N reported this event through the OPTN Improving Patient Safety Portal.

OPO 02412N allocated the lungs, heart, liver, pancreas, left kidney, and right kidney from a donor who had undergone massive transfusion with ABO O blood products. The OPO subsequently determined that the donor was ABO O. Testing later revealed that the donor was actually ABO A1.

Hospital 41473N received the heart and transplanted it into an ABO B recipient. After release of crossclamp, the heart stiffened and became edematous. Hospital 41473N was unable to get the recipient off of CPB, and converted to VA ECMO. After six days the heart recipient was re-transplanted. The heart recipient is doing well and was discharged home 22 days after the second transplant.

Hospital 46029N received the liver and transplanted it into an ABO O recipient. The recipient is doing well and is not expected to have an adverse course related to the incompatible ABO.

Hospital 35577N received the pancreas for an ABO O recipient. Using blood taken during procurement, Hospital 35577N re-ran donor ABO and found a mix of A and O blood types. Hospital 35577N called OPO 02412N and was informed of the massive transfusion the donor received, and that OPO 02412N had one indeterminate blood typing result. Hospital 35577N aborted the procedure and did not transplant the intended recipient. The pancreas was later discarded.

Hospital 03283N received the lungs, the left kidney, and the right kidney. The lungs were transplanted into an ABO O recipient who showed immediate signs of rejection and was put on ECMO. The lung patient died the next day.

The left kidney was transplanted into an ABO O recipient. The graft is functioning well and Hospital 03283N believes that the ABO incompatibility will not affect graft function.

The right kidney was discarded after the ABO discrepancy was found.

Relevant OPTN Policy:
2.6.A <u>Deceased Donor Blood Type Determination:</u> "The host OPO must develop and comply with a written protocol to resolve conflicting primary blood type results."

Donor Analysis: The donor was a [redacted] who was in a motor cycle collision with head trauma. There was no available pre-transfusion admission blood on which ABO typing could be performed.

The donor was 5' 6" tall and weighed 130 pounds, resulting in an estimated total plasma volume of 2356.00 mls and an estimated total blood volume of 3926.67 mls. The massive transfusion of

12 units of PRBC, 10 units of FFP, and 3 units of platelets resulted in administration of 3700.00 mls of plasma products and 3000.00 mls of blood products.

Relevant Correspondence:
Inquiry to OPO 02412N - sent on December 10, 2018
Response from OPO 02412N - received on December 24, 2018
Second Inquiry to OPO 02412N - sent on December 26, 2018
Second Response from OPO 02412N - received on December 28, 2018
Notification letter to OPO 02412N - sent on January 4, 2019
Third Response from OPO 02412N - received on January 16, 2019

Member Response:

OPO 02412N reported:

- Pre-transfusion admission blood was hemolyzed and therefore unable to be utilized for ABO typing.
- The **first ABO** was drawn post-transfusion. This sample was "run on the Ortho-Vision Analyzer" and had an indeterminate result. The blood bank technician ran forward and reverse testing, which resulted in a forward ABO of O and a reverse ABO of A. The blood bank reported the ABO as O "since it is hospital policy that the forward results indicate the red blood cells and reverse could be impacted by the fresh frozen plasma" a patient receives during transfusion.
- The donor hospital also does not report indeterminate results per internal policy, so the OPO was not aware of the initial indeterminate result.
- More blood was drawn and was sent to an outside lab for serology testing. This lab also found indeterminate ABO results with forward typing indicating ABO O and negative reverse typing indicating ABO A. This was the **second ABO** result.
- Had OPO 02412N known that the first ABO typing was also indeterminate in addition to the second typing at the serology lab, this would have been a "red flag."
- A **third ABO** was drawn at the donor hospital and resulted in a forward and reverse typing of ABO O. OPO 02412N considered this ABO as confirmation of the first ABO and a resolution of the discrepant ABO typing found at the outside lab.
- The Clinical Allocation Technician (CAT) notified the Clinical Donation Coordinator (CDC) and the Administrator on Call (AOC) of the indeterminate results. "Given that there were two" ABOs drawn at the donor hospital "on different dates with the same results" the "AOC did not notify the Medical Director of the 'indeterminate' results."
- The CAT uploaded the two ABO O results into DonorNet and these were verified by the AOC.
- The CAT notified each transplant coordinator that the donor was hemodiluted and therefore PHS Increased Risk. "Given that there were two" ABOs drawn at the donor hospital "on different dates with the same results" the CAT "did not notify the transplant programs" of the indeterminate ABO result. This information was also not specifically called out in DonorNet, however, the indeterminate ABO was available on the serology results attachment.
- The day after procurement, Hospital 35577N contacted OPO 02412N to alert them that the blood sent with the pancreas resulted in ABO A. OPO 02412N then alerted the

other receiving centers, but the heart, lungs, liver, and left kidney had already been transplanted.

- The Root Cause Analysis determined no human errors, no staff training or competency issues, and that both OPO 02412N and the donor hospital followed all internal, OPTN, and CMS policies related to ABO typing.
- 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 [donor] hospital Blood Bank process and donation area process for allocation."
- At the time of the event, OPO 02412N "did not have a clear process for when an indeterminate result was communicated" besides "either drawing another sample or checking for an available sample."
- At the time of the events, OPO 02412N "did not have a clear process" for when an indeterminate result should be escalated.

OPO 02412N corrective actions:

- An immediate containment plan was initiated: If blood typing results for any test indicate indeterminate results, or if the donor has "been on a massive transfusion protocol," OPO 02412N will immediately "place further management of the case" on "hold" until the 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 indeterminate results on the donor evaluation and organ allocation."
- The Chief Clinical Officer developed the "Hard Stop Playbook" which outlines when hard stops will be implemented. This playbook was emailed to pertinent staff and reviewed during a staff meeting.
- OPO 02412N will monitor 100% of cases of indeterminate results and massive transfusion protocol for documentation of discussion between the AOC and Medical Director.

SFC OPTN Hearing
Exhibit B.6

Improving Patient Safety

Safety Situation [redacted]

The goal of the Improving Patient Safety system is to collect information about safety related incidents occurring system-wide, in order to increase organ utilization and decrease the morbidity and mortality of transplant patients.

What is a Safety Situation?
A situation or activity that affected or could have affected patient safety.

What to report:

- Any patient safety situation
- Any other situation that causes a safety concern from a transplantation, donation, and/or quality perspective.

Please report such situations in a timely manner.

Related

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Below you will find the most current information for situation [redacted] You can complete the following tasks on this page:

- Access a printer-friendly version of this safety situation
- Add resolution information

Situation Information

Reporting Institution: * [redacted]-Transplant Hospital(Member)

Type of Safety Event (Choose all categories and subcategories that are applicable): *

- [ ] Communication
- [ ] Data Entry
- [ ] Transportation
- [ ] Packaging/Shipping
- [x] Labeling
  - [x] ABO
  - [ ] Donor ID
  - [ ] Required information missing
  - [ ] Transcription error
  - [ ] Switched laterality for Labeling
  - [ ] Incorrect test results
  - [ ] Blood/nodes/spleen labeling issue
  - [ ] Missing label
  - [ ] Other (please describe in the description field below)
- [ ] Recovery Procedure/Process
- [ ] Transplant Procedure/Process
- [x] Testing
  - [x] ABO
    - [x] ABO error or discrepancy
    - [ ] ABO misinterpretation
    - [ ] ABO subtyping error or discrepancy
    - [ ] ABO subtyping misinterpretation
    - [x] Blood transfusion caused misleading results
    - [ ] Switched samples
    - [ ] Switched source documentation
    - [ ] Inadequate sample for testing
    - [ ] Other (please describe in the description field below)
  - [ ] HLA
  - [ ] Infectious Disease
  - [ ] Other (please describe in the description field below)
- [ ] Organ Allocation/Placement
- [ ] Other (please describe in description field below)

SFC OPTN Hearing Exhibit B.6

The Issue reported involves the following (choose all categories that are applicable): *

- [x] **Recipient/Candidate**
  - **Waitlist ID:** [redacted] **No Waitlist ID:** [ ]
- [ ] **Donor Organ/Extra Vessels**
- [ ] **Other (please describe in the description field below)**

Date Event Occurred: * 11/27/2018

Detailed Description of the Event: * Patient received heart from donor that was high risk secondary to hemodilution. ABOs ran as O neg, recipient B. ABO from 11/24 (date of injury) and 11/25. Serology ABO was apparently indeterminate, also done on 11/25. No details of this finding on donor summary page. Heart stiff and edematous once off cross clamp, unable to get off CPB, converted to VA ECMO. Recipient remains on VA ECMO at this time. Notified by donor OPO[redacted] at 0300 this morning that pancreas team ran ABO and was A. We then ran an ABO here which also revealed ABO to be A.

Has a root cause analysis (RCA) been completed? * ( ) **Yes** (•) **No** ( ) **In Progress**

Please specify additional details regarding the RCA: RCA will be done but hasn't been started as we were just notified of issue at 0300 today.

Please upload any relevant attachments:

Contact Information

Who at your institution should UNOS contact about this case?

First Name: * [redacted] **Last Name:** * [redacted]

Phone contact (Enter at least one): *

Office: [redacted] **ext.** **Pager/beeper:** **ext.**

Mobile: [redacted] **ext.** **Other:** **ext.**

Email: * [redacted]

Other contact info:

UNOS Only

Reported by: [redacted]

Initial UNOS Action

Date: * 11/28/2018 **Staff member:** [redacted]

Status: * In process **Urgency:** * Medium

Category: * Critical

Potential policy violation: ( ) **YES** ( ) **NO**

Committee notification? ( ) **YES** ( ) **NO**

Type of Safety Event (Choose all categories and subcategories that are applicable):

- [ ] **Communication**
- [ ] **Data Entry**
- [ ] **Transportation**
- [ ] **Packaging/Shipping**
- [ ] **Labeling**
- [ ] **Recovery Procedure/Process**
- [ ] **Transplant Procedure/Process**
- [ ] **Testing**
- [ ] **Organ Allocation/Placement**
- [ ] **Other (please describe in description field below)**

Attachments

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Correspondence/Comments

Add

Comment	Date	User

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SFC OPTN Hearing Exhibit B.6

[redacted]

Choose an application

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Help

Improving Patient Safety

Safety Situation [redacted]

The goal of the Improving Patient Safety system is to collect information about safety related incidents occurring system-wide, in order to increase organ utilization and decrease the morbidity and mortality of transplant patients.

What is a Safety Situation?
A situation or activity that affected or could have affected patient safety.

What to report:

- Any patient safety situation
- Any other situation that causes a safety concern from a transplantation, donation, and/or quality perspective.

Please report such situations in a timely manner.

Below you will find the most current information for situation [redacted]. You can complete the following tasks on this page:

- Access a printer-friendly version of this safety situation
- Add resolution information

Situation Information

Reporting Institution: * [redacted]-Transplant Hospital(Member)

Type of Safety Event (Choose all categories and subcategories that are applicable): *

- [ ] Communication
- [x] Data Entry
  - [x] DonorNet
    - [ ] Donor ID
    - [ ] Demographics (e.g., height, weight, age, ethnicity)
    - [x] ABO
    - [ ] ABO Subtyping
    - [ ] HLA
    - [ ] Labs (e.g., creatinine, INR)
    - [ ] Infectious disease test result(s)
    - [ ] Increased risk (or high risk) status of donor
    - [ ] Other (please describe in the description field below)
  - [ ] Waitlist
  - [ ] Other (please describe in the description field below)
- [ ] Transportation
- [ ] Packaging/Shipping
- [ ] Labeling
- [ ] Recovery Procedure/Process
- [ ] Transplant Procedure/Process
- [ ] Testing
- [x] Organ Allocation/Placement
  - [ ] Offer rescinded
  - [ ] Offer not made to secondary contact
  - [ ] Out of sequence allocation
  - [ ] Inaccurate patient priority or status
  - [ ] Recipient not on match run
  - [ ] Inaccurate donor data caused match to run incorrectly
  - [ ] Match not rerun once serology found to be positive
  - [x] Other (please describe in the description field below)
- [ ] Other (please describe in description field below)

The Issue reported involves the following (choose all categories that are applicable): *

- [x] **Recipient/Candidate**

SFC OPTN Hearing Exhibit B.6

Waitlist ID: **No Waitlist ID:** ☑

SSN: * [redacted]

☑ **Donor Organ/Extra Vessels**

Donor ID associated with the event: * [redacted]

Did this event involve the entire donor or were only specific organs involved? * Entire Donor

Organ Type

- ☐ Right Kidney
- ☐ Left Kidney
- ☐ Double/En-bloc Kidney
- ☐ Pancreas
- ☐ Pancreas Segment 1
- ☐ Pancreas Segment 2
- ☐ Liver
- ☐ Liver Segment 1
- ☐ Liver Segment 2
- ☐ Intestine
- ☐ Intestine Segment 1
- ☐ Intestine Segment 2
- ☐ Heart
- ☐ Right Lung
- ☐ Left Lung
- ☐ Double/En-bloc Lung
- ☐ Extra Vessel(s)

Did this safety situation cause or contribute to:

The non-recovery of organ(s)? * Unknown

The discard of any organ(s)? * Unknown

A delay (prolonged ischemic time) for any organ(s) transplanted? * Unknown

☐ **Other (please describe in the description field below)**

Date Event Occurred: * 11/27/2018

Detailed Description of the Event: * [redacted] accepted donor organ [redacted] for our recipient. All OPO and DonorNet data stated this donor was ABO O, which was compatible with our recipient. After transplantation occurred, we were notified that the donor's ABO was actually A, making the donor incompatible with our recipient. We are now following our own ABO incompatible protocol in an attempt to manage this recipient and organ.

Has a root cause analysis (RCA) been completed? * ○ Yes ◉ No ○ In Progress

Please specify additional details regarding the RCA: We were just made aware of this event this morning; no RCA has been able to be completed yet.

Please upload any relevant attachments:

Contact Information

Who at your institution should UNOS contact about this case?

First Name: * [redacted] **Last Name:** * [redacted]

Phone contact (Enter at least one): *

Office: [redacted] **ext.** **Pager/beeper:** **ext.**

Mobile: **ext.** **Other:** **ext.**

Email: * [redacted]

Other contact info:

UNOS Only

Reported by: [redacted]

Initial UNOS Action

Date: * 11/28/2018 **Staff member:** [redacted]

Status: * In process **Urgency:** * Medium

Category: * Critical

Potential policy violation: ○ YES ○ NO

Committee notification? ○ YES ○ NO

Type of Safety Event (Choose all categories and subcategories that are applicable):

- ☐ Communication
- ☐ Data Entry
- ☐ Transportation

SFC OPTN Hearing Exhibit B.6

- Packaging/Shipping
- Labeling
- Recovery Procedure/Process
- Transplant Procedure/Process
- Testing
- Organ Allocation/Placement
- Other (please describe in description field below)

Attachments

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Correspondence/Comments

Add

Comment	Date	User

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print=Y&id=101520&TRKR=tv7nhlZPMWyvTBFUbclmcyoQ2B1vllZK56nIT9LacJ3Vl%2F4FAKtrHQ%3D%3D&CTXT=tv7nhlZPMWyvTBFUbclmcyoQ2B1vllZK56nIT9LacJ3Vl%2F4FAKtrHQ%3D%3D)

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[redacted]

Choose an application

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Help

Improving Patient Safety

Safety Situation [redacted]

The goal of the Improving Patient Safety system is to collect information about safety related incidents occurring system-wide, in order to increase organ utilization and decrease the morbidity and mortality of transplant patients.

What is a Safety Situation?
A situation or activity that affected or could have affected patient safety.

What to report:

- Any patient safety situation
- Any other situation that causes a safety concern from a transplantation, donation, and/or quality perspective.

Please report such situations in a timely manner.

Related

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Below you will find the most current information for situation[redacted] ou can complete the following tasks on this page:

- Access a printer-friendly version of this safety situation
- Add resolution information

Situation Information

Reporting Institution: * [redacted]-Transplant Hospital(Member)

Type of Safety Event (Choose all categories and subcategories that are applicable): *

- [ ] Communication
- [ ] Data Entry
- [ ] Transportation
- [ ] Packaging/Shipping
- [ ] Labeling
- [ ] Recovery Procedure/Process
- [ ] Transplant Procedure/Process
- [x] Testing
  - [x] ABO
    - [x] ABO error or discrepancy
    - [ ] ABO misinterpretation
    - [ ] ABO subtyping error or discrepancy
    - [ ] ABO subtyping misinterpretation
    - [ ] Blood transfusion caused misleading results
    - [ ] Switched samples
    - [ ] Switched source documentation
    - [ ] Inadequate sample for testing
    - [ ] Other (please describe in the description field below)
  - [ ] HLA
  - [ ] Infectious Disease
  - [ ] Other (please describe in the description field below)
- [ ] Organ Allocation/Placement
- [ ] Other (please describe in description field below)

The Issue reported involves the following (choose all categories that are applicable): *

- [x] **Recipient/Candidate**
  Waitlist ID: [redacted] **No Waitlist ID:** [ ]
- [ ] **Donor Organ/Extra Vessels**
- [ ] **Other (please describe in the description field below)**

Date Event Occurred: * 11/27/2018

Detailed Description of the Event: * Pancreas accepted from UNOS[redacted] Donor was allocated as blood type O. Patient in OR 11/27/18 2305, induction 2320, initial incision 2349. Tissue was labeled as O when received by blood bank. 2339 received notification that the corresponding blood sample was typed in our blood bank as A- mixed field (i.e. some donor sample RBCs were A, some were O). Surgeon notified and procedure put on hold. The transplant coordinator phoned host OPO ([redacted]) and was told the donor was hemdiluted due to massive volume of blood products. OPO reported ABO verification was completed after transfusions on 11/24 and 11/25 both O. Third ABO 11/26 was "indeterminate" with O and some A. This was not disclosed at the time of

SFC OPTN Hearing Exhibit B.6

allocation. [redacted] nurse coordinator contacted donor hospital and learned donor received 2500 CC of RBC's prior to 1st typing. 0102 We contacted host OPO again requesting additional information and were notified that other recipient OPO are getting the same indeterminate ABO. 0159 received report that the lung recipient is having complications consistent with ABO incompatibility. At this time we aborted the case.

Has a root cause analysis (RCA) been completed? * ○ Yes ◉ No ○ In Progress

Please specify additional details regarding the RCA:

Please upload any relevant attachments:

Contact Information

Who at your institution should UNOS contact about this case?

First Name: * [redacted] **Last Name:** * [redacted]

Phone contact (Enter at least one): *

Office: [redacted] ext. **Pager/beeper:** ext.

Mobile: ext. **Other:** ext.

Email: * [redacted]

Other contact info:

UNOS Only

Reported by: [redacted]

Initial UNOS Action

Date: * 11/28/2018 **Staff member:** [redacted]

Status: * In process **Urgency:** * Low

Category: * Critical

Potential policy violation: ○ YES ◉ NO

Committee notification? ○ YES ◉ NO

Type of Safety Event (Choose all categories and subcategories that are applicable):

- ☐ Communication
- ☐ Data Entry
- ☐ Transportation
- ☐ Packaging/Shipping
- ☐ Labeling
- ☐ Recovery Procedure/Process
- ☐ Transplant Procedure/Process
- ☐ Testing
- ☐ Organ Allocation/Placement
- ☐ Other (please describe in description field below)

Attachments

Choose File No file chosen

Maximum File Size 20MB

Correspondence/Comments

Add

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UNOS
UNITED NETWORK FOR ORGAN SHARING

Matching organs. Saving lives.

[redacted]

CONFIDENTIAL MEDICAL PEER REVIEW

December 10, 2018

VIA SECURE EMAIL

[redacted]

Dear [redacted]:

The United Network for Organ Sharing (UNOS) serves as the Organ Procurement and Transplantation Network (OPTN) under contract with the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services. Under that contract, UNOS staff review reported or identified patient safety and/or public health-related concerns associated with organ donation and transplantation occurring within the OPTN.

UNOS' Member Quality staff screen all reports to determine whether the matter suggests a risk or threat to patient safety or public health. Often additional information is needed from the involved OPTN member(s) to finalize the assessment of threat. If the matter is assessed as both time-sensitive and serious, this department will alert OPTN leadership and, under that direction, work with OPTN member(s) to alleviate the threat.

UNOS' Member Quality Department staff also screen all reports to determine if there is a possible violation of OPTN/UNOS bylaws or policies associated with the matter. Again, additional information is typically needed from OPTN member(s) involved in order to complete the assessment.

We are currently reviewing an ABO typing error at [redacted] for donor [redacted] Our preliminary analysis indicates that the donor was typed as ABO O after a massive transfusion in the donor hospital. The donor was assigned and matches executed using ABO O. The ABO assignment process did not appear to account for the transfusion.

We are contacting you to obtain a complete understanding of what occurred. We appreciate as much detail as you can provide. Any information you provide that suggests a potential policy or bylaw violation, or which may pose a threat to transplant or donor patient health or public safety

[redacted]

may be referred for review by OPTN leadership, including the Membership and Professional Standards Committee (MPSC), and in some cases the OPTN Board of Directors.

Please address the following issues related to the ABO typing of this donor:

- Provide a detailed review and timeline of the ABO typing for this donor including:
  - A description of the samples used to determine ABO, including if each sample was pre- or post-transfusion;
  - All ABO typing tests, including any indeterminate testing;
  - When and how the typing error was identified;

- Provide a root cause analysis, if available.

- Provide a complete record of transfusions and a copy of the hemodilution calculation worksheets for this donor.

- Was the [redacted] Medical Director, donor hospital blood bank, AOC, or any other individual consulted about the ABO interpretation?

- Describe what was initially entered into DonorNet and communicated to the receiving centers about the donor's ABO and transfusion history. Specifically address any communication regarding the indeterminate typing.

- Provide a review of the communication to the receiving centers about the ABO typing. Describe the status of each organ (i.e., transplanted, pre-transplant) at the time each center learned of the issue.

- Provide your Standard Operating Procedure and/or policy for donor ABO typing. Include any quality assurance steps and tools or resources that are used to assign donor ABO when blood is drawn post-transfusion.

- What corrective actions have been implemented or are planned to prevent recurrence of such an oversight? Include any documentation that supports these corrective actions, such as revised policy, staff re-training or education materials, etc.

The OPTN bylaws and policies guide the sequence of allocation and wait listing practices of OPTN members in an effort to assure equitable organ allocation for transplant. The bylaws and policies also guide safe and effective practice connected to organ transplantation and living donor care. UNOS is responsible for monitoring compliance by OPTN members with these OPTN obligations, as well as for processing reports of transplant-related patient safety and living donor safety.

The MPSC, and in certain cases, the OPTN Board of Directors, perform the peer review functions of the OPTN. Please be aware that this correspondence and all documents and information requested by UNOS staff, on behalf of the OPTN, are protected by applicable peer review statutes and will not be disclosed. For this reason, all associated reports, inquiries, deliberations, findings, recommendations, and actions must be kept confidential. This means we will not be able to provide you with the results of our investigation.

I look forward to hearing from you by **December 24, 2018**. Responses can be sent via mail email and/or fax. I can be contacted at [redacted] Thank you in advance for providing the additional information requested.

Sincerely,

[redacted]
Safety Analst UNOS
Member Quality

cc: [redacted]

[redacted]

From: [redacted]
Sent: Monday, December 24, 2018 3:32 PM
To: [redacted]
Cc: [redacted]

Subject: [redacted] Response
Attachments: [redacted] UNOS Response 12.24.2018.pdf; Appendix B.pdf; Appendix C.pdf; Appendix D.pdf; Appendix E.pdf; Appendix A.pdf

[redacted]

Attached you will find:

[redacted] Response to UNOS letter

Appendix A-E as outlined in the response letter.

If you have any questions or need additional information, please contact me via email at [redacted] .

Merry Christmas and a safe Happy New Year.

[redacted]
Director Quality Systems

[redacted]
Office [redacted] :: Fax [redacted] ::

[redacted]

[redacted]

December 24, 2018

[redacted]
Safety Analyst
UNOS Member Quality
United Network for Organ Sharing
[redacted]

Dear [redacted],

We are in receipt of your letter dated December 10, 2018 regarding Donor ID [redacted] requesting a complete understanding of what occurred. In your letter you requested that we address the following issues related to the ABO typing of this donor:

- Provide a detailed review and timeline of the ABO typing for this donor including:
  - A description of the samples used to determine ABO, including if each sample was pre- or post-transfusion;
  - All ABO typing test, including any indeterminate testing;
  - When and how the typing error was identified.

[redacted]**Response:**

Appendix A includes the detailed review with timeline of the ABO typing for Donor AFKY198.

- The samples used to determine the donor ABO typing were obtained post-transfusion. ABO# 1 was drawn on 11/24/2018 at 23:09 at the donor hospital and the results indicated "O" negative, ABO #2 was drawn at 11/25/2018 at 19:50 at the donor hospital and results were also "O" negative.
- The serology sample sent to VRL for donor eligibility testing included ABO typing. The sample was drawn on 11/25/2018 at 19:00 post-transfusion and the final results for ABO typing were "indeterminate" on 11/26/2018 at 13:49.
- On 11/28/2018 at 01:38 the [redacted] Communication Center received a call from transplant center that accepted the pancreas that when they re-ran the sample that accompanied the pancreas their ABO testing results were "A". The Communication Center notified the OAOC of the call.

- Provide a root cause analysis, if available.

[redacted]**Response:**

[redacted] is currently working on the root cause analysis of this incident. We are pending a RCA meeting with the donor hospital tentatively scheduled for January 10, 2019. We are also planning on conducting a joint RCA meeting with the donor hospital, [redacted] transplant program and [redacted]. This meeting will be schedule for early January 2019.

- Provide a complete record of transfusion and a copy of the hemodilution calculation worksheet for this donor.

[redacted] **Response:**

Appendix B includes the record of the transfusions and the hemodilution calculation worksheet.

- Was the [redacted] Medical Director, donor hospital blood bank, AOC, or any other individual consulted about the ABO interpretation?

[redacted] **Response:**

The Clinical Allocation Technician (CAT) notified the Clinical Donation Coordinator (CDC) and the AOC of the "indeterminate "results from VRL. The AOC was notified by text message and email on 11/26/2018 at 02:29 that the ABO typing was uploaded to DonorNet and that the VRL results were "indeterminate" based on the documentation from the VRL report. Given that there were two hospital ABO drawn on different dates with the same results of "O "negative, so the AOC did not notify the Medical Director of the "indeterminate" results.

- Describe what was initially entered into DonorNet and communicated to the receiving centers about the donor's ABO and transfusion history. Specifically address any communication regarding the indeterminate typing.

[redacted] **Response:**

The CAT entered the 'O" results and uploaded the two hospital ABO into DonorNet on 11/26/2018 at 14:29. The CAT notified the AOC that the ABO results were uploaded to Donor Net via text and email. The AOC verified the "O "negative ABO typing in Donor Net on 11/26/2018 at 15:00.

During allocation of each organ the CAT notified each transplant coordinator that the donor was hemodiluted and was placed as a high risk donor based on the PHS classification for hemodilution. The recovery surgeons each signed the High Risk Disclosure form. . Given that there were two hospital ABO drawn on different dates with the same results of "O "negative, the CAT did not notify the transplant programs of the "indeterminate" results.

Appendix C includes:

- DonorNet verification documentation

[redacted]

- CAT ABO verification form- [redacted]O 1.110-5 CAT ABO Verification
- Signed High Risk Disclosure Form- [redacted]O 3.033-1 High Risk Disclosure

- Provide a review of the communication to the receiving centers about the ABO typing. Describe the status of each organ (i.e., transplanted, pre-transplant) at the time each center learned of the issues.

[redacted] **Response:**

The CAT during the allocation process notified each transplant program of the donor ABO typing results of "O" negative.

The status of each organ at the time [redacted] was made aware and notified each program of the discrepancy is outlined below:

Lung- [redacted] transplanted
Heart- [redacted] transplanted
Liver- [redacted] transplanted
Pancreas- [redacted] pre-transplanted- discarded after notification
Right Kidney- [redacted] pre-transplanted- discarded after notification
Left Kidney- [redacted] transplanted

- Provide your Standard Operating Procedures and/or policy for donor ABO typing include any quality assurance steps and tools or resources that are used to assign donor ABO when blood is drawn post-transfusion.

[redacted] **Response:**

See Appendix D

- What corrective actions have been implemented or are planned to prevent recurrence of such an oversight? Include any documentation that supports these corrective actions such as revised policy, staff re-training or education materials, etc.

[redacted] **Response:**

The [redacted] Executive team including the Directors of Quality Systems and Communication and the Medical Director and Associate Medical Director met on 11/28/2018 at 08:30 and developed the containment plan to be implemented immediately.

[redacted] **Containment Plan to the ABO Incident**

Indeterminate ABO typing- if blood typing results - for any test - indicates that the sample results are indeterminate- [redacted] will immediate place further management of the case on

[redacted]

"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, [redacted] 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.

The Containment Plan was communicated to the AOC and CDC III in a meeting held on 11/28/2018 at 11:30am.

The Containment Plan was communicated to [redacted] Quality Analyst at UNOS on 11/29/2018 at 13:00 via email.

The Chief Clinical Officer developed the [redacted] Hard Stop Playbook (see Appendix E) which outlines when hard stop will be implemented. Hard Stop Playbook was emailed to the Organ Recovery Services Managers (Clinical Donation Coordinators, Clinical Allocation Technicians and Clinical Donation Specialists. The Clinical Recovery Manager reviewed the Hard Stop Playbook with Clinical Donation Coordinator and Clinical Allocation Technicians on December 13, 2018 during their staff meeting.

If you have any questions or need additional information, please contact me [redacted] Director of Quality Systems at [redacted] or via email at [redacted].

Sincerely,

[redacted]
Director Quality Systems
[redacted]

Appendix A

[redacted]

11/25/Donor ID [redacted]
UNOS ID [redacted]
Tissue ID [redacted]

Donor Demographics:
[redacted]
DOB [redacted]
H/W- 66 inches / 129.9 lbs BMI 21.0

Hospital Course:
24 year old female presented to [redacted] ER as a Level 1 trauma, s/p helmeted motorcycle collision vs tree. She was unresponsive en route, requiring CPR pre-hospital but obtained ROSC. On arrival to ER at 11/24/2018 21:08, bilateral chest tubes were inserted in the trauma bay and massive transfusion protocol was initiated. She was noted to have an injury related deformity of the right arm as well as an open bleeding wound of the pelvis. She was emergently taken to the OR for an ex lap.

In OR, a grade 1 liver laceration was electrocauterized to maintain hemostasis. She lost pulses intraoperatively with CPR being initiated, a pericardial window was performed showing no hemopericaridum tamponade. Her abdomen was packed with 27 lap pads for hemostasis. Following the initial resuscitation, CT scan of head, neck, chest and abdomen was obtained showing innumerous injuries to the extremities, C-spine, T spine, thorax and most notably cerebral edema and downgoing transtentorial and tonsillar herniation inconsistent with life.

She was admitted to the STICU in critical condition with ongoing resuscitation with blood products and hemodynamic support with pressors. Neurosurgery was consulted and in agreement with CT finding of her neurological injuries would not be survivable. She was taken off sedation and found to be completely areflexic, without a gag reflex or cough reflex, no corneal response, no oculocephalic reflex and without response to painful stimuli. Apnea test was performed indicating no spontaneous respirations. She became increasingly hypotensive so a CTA brain perfusion was performed at 16:34 to confirm brain death. Patient was pronounced at 16:34 on 11/25/2018.

Case Timeline:

Timeline		Case Details
11/24/18	2108	Arrived [redacted] ER
11/24/18	2200	Taken to OR- exp. lap • Grade 1 liver laceration • Pericardial window with no evidence of tamponade • Injuries to extremities, c-spine, t-spine and thorax

[redacted]

		• Cerebral edema with downgoing transtentorial and tonsillar herniation. **Emergency Department and Intraoperative transfusions:10 units PRBC** **6 units FFP** **2 units of pooled platelets** Transferred to STICU
11/24/18	22:55	Referral to [redacted] by STICU RN – clinical triggers met 22:37 Neuro Status: GCS 3 Pain: no response Pupillary response: none Cough/gag reflex: none Over-breathing the vent: no Hypothermic protocol: No Sedation/Paralytics: none
11/24/18	23:04	AOC [redacted] notified
11/24/18	**23:09**	**ABO #1- Hospital ABO: O negative**
11/24/18	23:53	Name verified M.D.
11/24/18	23:45	[redacted] onsite evaluation VS- HR 125, B/P 129/62. RR 22, 100% 95.5 F with bair hugger in place Levophed 30mcg/min, vasopressin 0.04 units/min
11/25/18	00:19	[redacted] Registry check- Registered
11/25/18	03:59	Family at bedside- prognosis discussed with hospital STICU attending
11/25/18	12:03	Apnea Test in progress. Plan for CTA to follow
11/25/18	13:40	Apnea is positive consistent with brain death
11/25/18	15:40	Tissue Eligibility Corneas MS/U/L Skin Bones Pelvis Heart values Hemocytes
11/25/18	**16:00**	CDC received call from Blood Bank verified that patient had received during this admission: **12 units PRBC** **10 units FFP** **3 units Platelets** **2 Cryo**
11/25/18	16:34	CTA performed – no blood flow- **pronounced**
11/25/18	16:34	Authorization disclosed to mother – parents request donor status be kept **CONFIDENTIAL.**

[redacted]

		Right/Left Kidney Liver Intestine Pancreas Heart Right/Left Lungs
11/25/18	**19:00**	**HLA and VRL blood drawn (serologies and ABO typing)** **Hemodilution Calculation Completed** **NOTE: Hemodilution calculation is conducted to evaluate the donor's serological risk for cross contamination due to hemodiluted sample. Donor was identified as increased risk for cross contamination due to hemodilution.**
11/25/18	19:10	DRAI/Addendum completed
11/25/18	19:37	Report called to [redacted] Medical Director] Dr. [redacted]. [redacted] Medical Director review process for initial suitability and disease transmission prevention with permission to begin the donation process.
11/25/18	**19:50**	**ABO#2 Hospital drawn – subsequent result: ABO- O negative**
11/26/18	01:54	Coroner requested admit blood and urine toxicology be held.
11/26/18	06:42	Clinical Allocation Technician (CAT) [redacted] received HLA results
11/26/18	06:54	HLA results verified with [redacted] HLA lab- [redacted] HLA to upload to Donor Net
11/26/18	07:00	VRL serologies pending
11/26/18	13:20	CAT [redacted] received call from Clinical Donation Coordinator (CDC) [redacted] asking for ETA on serologies. Informed that VRL had to rerun the NATs due to bad tray.
11/26/18	**13:49**	**VRL Report** **ABO/Rh (completed: 11/26/18 07:13) INDETERMINATE- Reference Range test- Ortho- Clinical ID- MTS Gel Test** **Comments: FORWARD AND REVERSE BLOOD TYPES ARE DISCREPANT** **FORWARD TYPE IS O NEGATIVE REVERSE IS A**
11/26/18	**14:07**	CAT- Serologies NAT report received. **Notified CDC that ABO's were indeterminate**. Informed CDC that there was an ABO result from Nov 24 23:09, so if he can find another ABO, if not we'll need to order another. Serologies report sent to CDC for entry, CAT will verify after entered.
11/26/18	14:20	CDC [redacted] entered serologies in iTx
11/26/18	**14:29**	**CAT [redacted] uploaded and entered ABO in DonorNet. Notified AOC of upload and need to verify ABO in Donor Net**
11/26/18	**14:32**	**CDC [redacted] sent ABO from Nov 26 to CAT**. CAT Completed ABO verification form ***O 1.110-5 CAT ABO Verification*** ABO Verification form and ABO's Sent to AOC [redacted] to let know CAT was ready for ABO verification. Forms attached to iTx and DonorNet.
11/26/18	14:35	CAT [redacted] Serologies verified

[redacted]

11/26/18	14:50	CAT [redacted]- List run: heart, lungs, kidney, panc (no intestines due to multiple pressors)
11/26/18	**15:00**	**AOC verifies ABO in Donor Net.**
11/26/18	15:59	CAT [redacted]- Conversation with CDC [redacted] regarding lists. Lung list has several HL at the top, so we will have to offer heart through Zone A and then start lung offers. [redacted] primary for kidneys and KP (which they have since declined). [redacted] primary for liver, [redacted] 2nd and also need a kidney. Per CDC, OR says if we don't get to OR by 2am we'll have to wait until 3 pm tomorrow
11/26/18	22:50	CDC [redacted] received call from CAT [redacted] [redacted] surgeon has called multiple times in an attempt to communicate how ill his patient is. He does not believe patient will live until OR if we have to wait until tomorrow afternoon. He has requested to be put in contact with OR charge RN to inform how sick potential recipient is.
11/26/18	23:03	CDC [redacted] called and spoke to OR Charge RN [redacted] Discussed current case status. He stated there is not much flexibility in the OR schedule and he does not believe he could accommodate us after 0200. We would therefore have to wait until after 1500 on 11/27/2018. He offered to put me in contact with his director. Told him I would discuss w/ OAOC and call him back.
11/26/18	23:22	CDC [redacted] called and discussed situation with OAOC [redacted]. She agreed that we would not allow accepting surgeon to communicate directly with referring hospital OR. She requested that I notify her if all organs are placed and OR does not have availability. She stated that the situation may need to be escalated to CEO [redacted] in the am if OR is not able to get us in the OR before tomorrow afternoon.
11/27/18	01:16	CDC [redacted] call placed to [redacted], RN in OR. Notified him that all organs are placed and inquired about setting an OR. He is unable to schedule OR for tomorrow. Stated we must wait for day shift charge RN to come in @ 0600 and schedule afternoon OR then. Updated CAT [redacted] She will contact OAOC [redacted].
11/27/18	01:27	CDC [redacted] called and obtained OR director's number. Updated OAOC [redacted]. She has reached out to CEO [redacted] and is awaiting a reply.
11/27/18	01:43	CDC [redacted]- OAOC asked to call CEO [redacted] and update him. Contacted [redacted] and explained current case status. Forwarded OR directors contact information. He will contact her.
11/27/18	02:03	CAT [redacted] was informed by CDC [redacted], CEO [redacted] spoke with Medical Director who finally agreed that we could go to Trauma overflow, and however, they need us to go ASAP.

[redacted]

11/27/18	02:19	CEO [redacted] s/w CDC ([redacted]) at approx. - 0135. He informed me that the Liver surgeon from [redacted] stated that they had a very sick recipient and needed to schedule the OR ASAP. The Donor Hospital has a rule that if [redacted] cannot schedule an OR before 0200, then we need to wait until the end of the next day to proceed with the recovery. Hospital personnel stated that they did not have the authority to schedule the OR outside this rule and that only the Director could approve. The hospital provided the name of the OR Director - [redacted], RN - to help with this issue. I s/w [redacted] and explained the situation. [redacted] gave us permission to use the trauma overflow OR to continue with the recovery. I re-contacted CDC [redacted] to let him know that we had this permission and that he may work to coordinate the OR scheduling with the incoming recovery teams.
11/27/18	03:30	Organ Disposition – CAT [redacted] HEART: [redacted] LUNGS : [redacted] LIVER: [redacted] PANCREAS: [redacted] INTESTINE: No list run,209 (Multiple pressors) KIDNEYS: 1 & 2 to [redacted] Tissue WILL follow, however may have to go after 3pm. All Accepting centers will need to sign the High Risk Disclosure form. I will have [redacted] sign and fax for pancreas and [redacted] for kidneys.
11/27/18	04:00	CDC [redacted] - OR and **Tissue blood drawn**
11/27/18	04:21	OR time set for 06:00
11/27/18	16:40	Clinical Donation Specialist [redacted] 0720- Arrived at OR and began preparations for recovery Heart team from [redacted] had delayed arrival due to traveling to the wrong airport 0800- Timeout and moment of honor 0802- Incision Cross clamp- 0930 0942- Heart out everything was fine and good condition 0954- Lungs out everything in good condition 1008 -Liver out, but Surgeon very adamant about sending Liver out immediately upon removal. Surgeon sent Liver with Resident to go back to Hospital in [redacted]. The liver went out without Vessels. We had to wait until surgeon removed remaining organs to

[redacted]

		retrieve Vessels and package them separately and sent them back with Surgeon Dr. [redacted]. 1008- Pancreas out and no problems 1051- Kidneys came out. The left kidney looked great. The right kidney did not look good. Doctor said it looked "dangerous". Hematoma on the lower posterior pole and mid pole hematoma. 1245- Closed donor, lines were not removed (due to coroner case). Donor, coroner pictures and donor personal belongings turned over to RN. 1301- Exit OR 1000 -Lungs were given to Dr. [redacted] 0950- Heart taken by Dr. [redacted] 1021- Liver was given to [redacted] 1147- Pancreas given to [redacted] 154-1 Left Kidney received by [redacted] 1542- Right Kidney received by [redacted]
Post Case Communication		
11/28/18	01:38	OAOC TA 11-28-2018 0052-received phone call from Comm Center; requesting to contact [redacted] at [redacted] in reference to blood typing. 0054-spoke to [redacted] and he stated "that the vessel and blood labels that accompanied the pancreas has a blood type of 'O', but when he runs the blood in the lab the blood type results yields an 'A'." He is worried about the discrepancy and wanted to contact about the situation. I told him that I will be immediately contacting my AOC about the matter. 0059- Contacted CDC [redacted] about the blood typing issue and that [redacted] would like a call back. She said she will need to speak with [redacted] about the concerns.
11/28/18	03:13	CAT [redacted] 01:38 Call from [redacted] regarding panc transplant in process. Her surgeon is in the OR with patient sedated but the ABO that came back from blood we sent is coming back A-. [redacted] has spoken with [redacted] who said that donor was receiving blood as soon as she entered ER and that ABO blood draw was after she'd received blood. They are wanting to know if there is any blood that was pre-transfusion that would be available for blood draw.
11/28/18	**03:24**	CAT [redacted] 02:10 Called AOC [redacted] and she said that other organs are having the same issue. She asked that I call blood bank and see what I can find out. Called [redacted] Blood Bank and spoke to [redacted]. She said first blood draw for ABO was 11/24/18 23:09 but donor had already received significant blood. They did

[redacted]

		two typing and came up O-. She said the other blood drawn at that time was set aside for coroner. I asked if there was any initial blood prior to transfusions that could be tested and she said there is not, that donor was receiving blood as soon as she hit the door. **Another tech, [redacted] called from Blood Bank to say that when they changed the name from Trauma Name they were required to do another ABO. She did it and it appeared that the Forward was A- with Reverse of O-. She said blood was hemolyzed, so she redid it and it came back O-.** Called this back to [redacted] and AOC [redacted] NOTE: The blood bank process of ABO testing and results reporting will be discussed during the Root Cause Analysis between [redacted] and [redacted] on 01/10/2019.
11/28/18	03:28	CAT [redacted] 03:02 Text from [redacted] asking how other recipients are doing with organs. Called AOC [redacted] who said that lung recipient is having issues consistent with incompatible ABO and one kidney pt is doing fine. AOC [redacted] said that she has a call out to Coroner Liaison [redacted] to see if the coroner would release his blood for typing, however per Blood Bank, it appears they have no pre transfusion blood. Called [redacted] back with these updates. Her surgeon is still in the OR, trying to determine how to proceed.
11/28/18	08:31	Text from [redacted] advising that they are aborting the panc transplant based on potential of incompatible ABO. They will discard locally. Her surgeon would like updates on heart and liver recipients when we have info.
11/28/18	03:59	OAOC [redacted] OAOC 0059- Incoming call from CDS [redacted] notifying me that [redacted] coordinator called and stated that they ran the donor ABO and it is resulting as an A blood type. ABO currently verified as O. 0108: Called AOC [redacted] and updated her on situation. Both hospital ABOs that were used to verify the ABO were drawn and typed after patient was massively transfused. Serology ABO was resulted as indeterminate. "FORWARD AND REVERSE BLOOD TYPES ARE DISCREPANT. FORWARD TYPE IS O NEGATIVE REVERSE IS A" 0128: Called and spoke with [redacted] coordinator [redacted]. He stated that they ran ABO on blood and vessels sent with pancreas and both are resulting as ABO A. Told him I would make some further phone calls and keep him updated.

[redacted]

		0137: Call to CEO [redacted] with this information. Instructed to call centers with all the information we currently have regarding potential ABO incompatibility. 0156: Called and spoke with Dr. [redacted] ([redacted] abdominal) and updated him on current situation. First kidney has been transplanted, their cross match was negative, and recipient is currently doing fine per MD. Asked Dr. [redacted] to please call [redacted] lab and have blood sent with kidney run an ABO STAT and to call me with results ASAP. 0201: Called and spoke with Dr. [redacted] ([redacted] lung & [redacted] medical director) and updated him on situation. Lung recipient status is poor and ABO incompatibility fits current clinical picture. Will update him with [redacted] lab ABO result. 0208: Called and spoke with [redacted] liver coordinator [redacted]. Advised her of current situation and possible ABO incompatibility. [redacted] will advise her surgeon and said I could expect a possible call back from them. 0226: Called and spoke with [redacted] ([redacted] heart transplant RN), advised her of current situation. She stated her recipient is on ECMO and not doing well and current clinical status is consistent with ABO incompatibility. She said the initial cross match was negative but the subsequent two have been positive. 0237: Updated [redacted] from [redacted] on current status and that I am waiting for [redacted] lab to run ABO off of blood sent with the kidney. 0308: Called [redacted] liver coordinator [redacted] and confirmed that her surgeon was aware of current situation. She said she has not spoken with an attending but that the resident on call stated the liver recipient was doing okay so far. 0336: Incoming call from Dr. [redacted] ([redacted] abdominal) stating [redacted] lab ABO came back as A negative. He asked what to do with second kidney as that kidney is still on the pump and has not been transplanted. 0340: Called CEO [redacted] and updated on blood type A negative. Because we do not have two different draw times to verify the ABO we cannot rerun lists. Second kidney and pancreas cannot be transplanted and are to be discarded. Called [redacted] with [redacted] and Dr. [redacted] with [redacted] to inform them we cannot run lists and the organs are to be discarded. Dr. [redacted] updated with ABO result.

[redacted]

11/28/18	04:18	OAOC [redacted] 0415: Called and spoke with [redacted] with [redacted] and let her know our ABO came back as A negative. She did not have any questions but stated she would probably follow up with me later this afternoon.
11/28/18	11:18	Called and spoke with [redacted] in the [redacted] blood bank. [redacted] blood bank ran ABO and subtyping off of the OR blood samples we sent with the kidney and donor blood type came back as A (1) negative.
11/28/18	12:37	OAOC [redacted] Late entry 11/28/18 0840: Spoke with the blood bank at [redacted] to inquire about whether or not the blood on hold for the coroner is pre-transfusion. The technician in the blood bank stated that the initial blood draw done at the hospital, upon admission, was all hemolyzed and therefore thrown away. The course of events were such that the pt. went from the ER, where she was massively transfused, to the OR. It was after the OR that another panel of blood work was drawn. So, there is no pre-transfusion blood in the hospital at all, including the coroner blood on hold.
11/28/18	15:29	CEO [redacted] Late Entry - approx. 0730 - s/w [redacted] Medical Director - Dr. [redacted] to inform her of the potential ABO determination error and the subsequent potential for incompatible ABO transplant(s).

Case Summary:

[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: [redacted]
LUNGS: [redacted]
LIVER: [redacted]
PANCREAS: [redacted]
INTESTINE: No list run, 209 (Multiple pressors)
KIDNEYS: 1 & 2 to [redacted]

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 [redacted] Communication Center received a call from transplant coordinator at [redacted] in reference to the donor blood typing. The call was referred to the Organ AOC. The AOC spoke with the

[redacted]

coordinator a t [redacted] who indicated they has tested the blood they received with the pancreas and the ABO came back "A". [redacted] 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. [redacted] 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.

Policy Review

UNOS Policy 2.2 OPO Responsibilities
14. Ensuring that documentation for all of the following deceased donor information is submitted to the OPTN Contractor upon receipt:
a. ABO source documentation
b. ABO subtype source documentation
c. Infectious disease results source documentation
d. Death pronouncement source documentation
e. Authorization for donation source documentation

[redacted] ***Response:*** [redacted] ***followed UNOS policy 2.2 section 14 by documenting the donor ABO and ABO subtype.***

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.

[redacted]

2. The tests completed on the hemodiluted specimens.
3. The hemodilution calculation used for the hemodiluted specimens, if requested.

[redacted] ***Response:*** [redacted] ***determined that due to the volume of blood products and the blood sample obtain post transfusion the donor was increased risk due to hemodilution.***

NOTE: Hemodilution calculation is conducted to evaluate the donor's serological risk for cross contamination due to hemodiluted sample. Donor was identified as increased risk for cross contamination due to hemodilution.

All centers were notified of the increase risk and sent the High Risk Disclosure form O 3.033-1 High Risk Disclosure for the recovering surgeon signature.

2.6 Deceased Donor Blood Type Determination and Reporting

Host OPOs must develop and comply with a written protocol for blood type determination and reporting that includes all of the requirements below.

2.6. A Deceased Donor Blood Type Determination

The host OPO must ensure that each deceased donor's blood type is determined by testing at least two donor blood samples prior to the match run. The host OPO must develop and comply with a written protocol to resolve conflicting primary blood type results.

Deceased donor blood samples must:

1. Be drawn on two separate occasions
2. Have different collection times
3. Be submitted as separate samples
4. Have results indicating the same blood type

The host OPO must document that blood type determination was conducted according to the OPO's protocol and the above requirements.

[redacted] ***Response: Blood type determination was completed using two different samples drawn on two separate occasion with the same results.***

ABO # 1 Drawn on 11/24/18 23:09
ABO #2 Drawn on 11/25/18 19:50

2.6. C Reporting of Deceased Donor Blood Type and Subtype

The deceased donor is not eligible for a match run until the host OPO completes verification and reporting as follows:

1. Two different qualified health care professionals, as defined in the host OPO's protocol, must each make an independent report of the donor's blood type to the OPTN Contractor.
2. If the donor's blood subtype will be used for allocation, a qualified health care professional must report the subtype to the OPTN Contractor. This report must be verified by a different qualified health care professional according to the OPO's protocol.

[redacted]

3. Both qualified health care professionals must use all blood type and subtype determination source documents to verify they:
a. Contain blood type and subtype (if used for allocation) results for the donor
b. Indicate the same blood type and subtype (if used for allocation) on the two test results
c. Match the result reported to the OPTN Contractor
The OPO must document that reporting was completed according to the OPO's protocol and the above requirements.
If donation must be accelerated to avoid organ waste, the host OPO may instead complete these requirements after the match run, but prior to organ release to a transplant hospital. The host OPO must document all of the following:
1. The reason that both blood type tests (and subtype tests, if used for allocation) could not be completed, verified, and reported prior to the match run.
2. If there are conflicting primary blood type test results, the host OPO must follow its protocol for resolving the discrepancy and must re-execute the match run if the final ABO result is different from the initial ABO on the original match run.
3. That all required blood type and subtype determinations, verification, and reporting were completed prior to organ release to a transplant hospital.

[redacted] ***Response: Verification of ABO was conducted by two qualified health professionals in DonorNet. The first independent verification occurred on 11/26/18 14:29 and the second verification occurred on 11/26/18 at 15:00. The verifications were done by the Clinical Allocation Technician and the Organ AOC.***

Centers for Medicare and Medicaid Services

Z178 (Standard) **§486.344(c) (3) Ensure that the potential donor's blood is typed using two separate blood samples.**
Interpretive Guidelines §486.344(c) (3)
Verify through the sample of donor records that two distinct samples of blood (e.g., during current patient admission and/or OPO evaluation) were collected from the donor at two different times and submitted as separate specimens for ABO blood typing. If one test was already performed by the hospital, then the OPO need only perform one additional test. "Split samples" (that is, submitting two specimens from a common sample derived from a single blood sample collection) do not meet this requirement.

Z181 (Standard) **§486.344(d) (2) (i) The OPO is responsible for two separate determinations of the donor's blood type;**
Interpretive Guidelines §486.344(d) (2) (i)
See § 486.344(c) (3)

[redacted]

[redacted] ***Response: Blood type determination was completed using two different samples drawn on two separate occasion with the same results.***
ABO # 1 Drawn on 11/24/18 23:09
ABO #2 Drawn on 11/25/18 19:50

Z182 (Standard) §486.344(d) (2) (ii) If the *identify (sic) of the intended recipient is known, the OPO has a procedure to ensure that prior to organ recovery, an individual from the OPO's staff compares the blood type of the donor with the blood type of the intended recipient, and the accuracy of the comparison is verified by a different individual; (*identify is a misprint in the regulation text and should be identity.)
Interpretive Guidelines §486.344(d) (2) (ii)
The OPO must have policies in place for compliance with OPTN requirements that, in cases where the recipient is known, two separate persons must compare the blood type of the donor and the blood type of the recipient. At least one verification must be performed by an OPO staff person.

[redacted] Response: Donor and recipient verification occurred in the OR with the intent surgeon and the [redacted] Qualified Health Professional for each organ on 11/27/18 07:55. The verification is documented on the ***O 4.020-2 Pre-Recovery Verification.***

Z183 (Standard) **§486.344(d) (2) (iii) Documentation of the donor's blood type accompanies the organ to the hospital where the transplant will take place.**
Interpretive Guidelines §486.344(d) (2) (iii)
Review the sample of the donor records to confirm that the OPO forwarded documentation of the donor blood type to the transplant hospital with the organ. This documentation should use an assigned identification number in lieu of the donor's name.

Z197 (Standard) **§486.346(c) The OPO must develop and follow a written protocol for packaging, labeling, handling, and shipping organs in a manner that ensures their arrival without compromise to the quality of the organ. The protocol must include procedures to check the accuracy and integrity of labels, packaging, and contents prior to transport, including verification by two individuals, one of whom must be an OPO employee, that information listed on the labels is correct.**
Interpretive Guidelines §486.346(c)
The OPO should develop its written protocols for packaging, labeling, handling and shipping organs and the protocols should be consistent with OPTN rule 5.0 Standardized Packaging and Transporting of Organ and Tissue Typing Materials.
The protocols must also require that an OPO staff member verify in writing that the ABO indicated on the container label and the donor information documents being sent with the organ are accurate. A second person, other than the person originally performing verification of the labeling and documentation requirements, must also verify their accuracy in writing. Review the sample of donor records to verify that the OPO has documentation to confirm that this double confirmation occurred and was documented.

[redacted]

Z 198 (Standard) **§486.346(d) All packaging in which an organ is transported must be marked with the identification number, specific contents, and donor's blood type.**
Interpretive Guidelines §486.346(d)
See §486.346(c)

[redacted] ***Response:***
[redacted] ***packaging of an organ includes any tissue typing materials, biopsy slides and documentation of ABO.***

Association of Organ Procurement Organization Standards

CL 4B.3 Documentation of ABO group (and subgroup, if applicable), weight and height. Blood group subtyping of ABO A donors (reference current UNOS/OPTN policy)
Interpretative Guidelines:
Look for evidence that when a blood type A or AB donor is subtyped and found to be non- A1 (negative for A1) or non A1B (negative for A1B), the OPO must complete a second determination subtype test to assess for the accuracy of the results. Blood samples for the initial and second determination subtype tests must be two separate determinations, either 1) two samples sent to two labs, or 2) two samples from separate draws sent to the same lab. Subtype testing must be performed only on pre-transfusion specimens. The two test results must indicate the same subtype before a match can be run using subtype to allocate organ.
When two pre-transfusion samples are not available, or the initial and second determination test results do not indicate the same subtype, the donor must be allocated based on the primary blood type and the subtype should not be entered into UNet℠. The OPO shall maintain documentation that the initial and second determination tests have taken place and make such documentation available for audit.
Each OPO shall establish and implement a procedure for two individuals to verify the accuracy of the initial and second determination subtyping test results by utilizing both ABO subtyping source documents and document that this process has taken place.

CL 6.6.1 Verification of donor ABO type/subtype if applicable.

[redacted] ***Response: The ABO subtype was not an issue in this case but the samples were two separate draws sent to the same hospital lab. Both samples were O negative.***

Post Case Root Cause Analysis and Communications

11/22/2018 08:30 Executive Team Meeting
Attendance:
[redacted] CEO

[redacted]

[redacted], CCO
[redacted], CFO
[redacted] Director Communication
[redacted] Director Quality Systems
[redacted] M.D. Medical Director
[redacted] M.D. Associate Medical Director

Discussion: Review of the incident and development of a containment plan to implement immediately.

11/28/2018 10:30am- AOC and CDC III Meeting
Attendance:
[redacted] Manager Clinical Recovery Service (CDCs/CATs)
[redacted] AOC
[redacted] AOC
[redacted] Director Communication
[redacted] RN CDC III
[redacted] RN CDC III
[redacted] RN CDC III
[redacted], CEO
[redacted] CCO

Discussion: Review of incident and communication of containment plan.

11/30/2018 15:30-Executive Team Update Meeting
Attendance:
[redacted], CEO
[redacted] CCO
[redacted] CFO
[redacted] Director Communication
[redacted] Director Quality Systems
[redacted], M.D. Medical Director
[redacted], M.D. Associate Medical Director

Discussion: Status update on containment plan, communication with regulatory and accrediting bodies.

12/5/2018 11:30 – [redacted] Blood Bank Meeting
Attendance:
[redacted], CEO

[redacted]

[redacted] M.D. Associate Medical Director
[redacted], M.D, Director [redacted] Transfusion Services/Blood Bank
[redacted], Director Quality Systems

Discussion: Informational meeting regarding blood bank practices and use of forward and reverse testing and definition of testing. Discussion also included the type and ABO typing of blood products administered in during massive transfusion protocols.

12/6/2018 11:30- Executive Team Meeting Update
Attendance:
[redacted] CEO
[redacted], CCO
[redacted], CFO
[redacted], Director Communication
[redacted], Director Quality Systems
[redacted], M.D. Medical Director
[redacted] M.D. Associate Medical Director

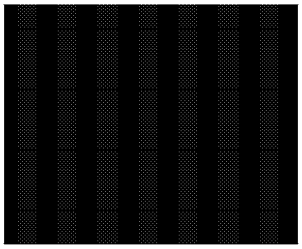
Discussion: Status update regarding meeting with [redacted] Blood Bank and updates regarding communication with regulatory and accreditation bodies.

12/11/2018 12n- [redacted] Governing Board of Directors Meeting
Attendance: (Existing)
[redacted] Chair
[redacted] M.D.
[redacted] M.D.
[redacted] M.D.
[redacted]

Discussion: Reviewed with the Governing Board of Director and incoming Governing Board members the ABO incompatibility case.

Pending RCA Meetings:

January 10, 2019 RCA between [redacted]



Transfusion of blood products within 48 hrs prior to specimen draw or asystole Date-Time Blood Type Volume
11/24/2018 21:25 Blood Product - RBC 500.0
11/24/2018 21:40 Blood Product - RBC 250.0
11/24/2018 22:14 Blood Product - RBC 250.0
11/24/2018 22:18 Blood Product - RBC 250.0
11/24/2018 22:20 Blood Product - RBC 250.0
11/24/2018 22:22 Blood Product - RBC 250.0
11/24/2018 22:50 Blood Product - RBC 250.0
11/24/2018 23:30 Blood Product - RBC 250.0
11/24/2018 23:40 Blood Product - RBC 250.0
11/25/2018 05:58 Blood Product - RBC 250.0
11/25/2018 05:58 Blood Product - RBC 250.0

Infusion of colloids within 48 hrs prior to specimen draw or asystole Date-Time Colloid Type Volume
11/24/2018 21:50 Colloid - Platelets 400.0
11/24/2018 22:10 Colloid - FFP/Plasma 600.0
11/24/2018 22:22 Colloid - FFP/Plasma 300.0
11/24/2018 22:26 Colloid - FFP/Plasma 300.0
11/24/2018 22:30 Colloid - FFP/Plasma 300.0
11/24/2018 22:35 Colloid - FFP/Plasma 300.0
11/24/2018 22:45 Colloid - Cryoprecipitate 100.0
11/24/2018 22:53 Colloid - FFP/Plasma 300.0
11/24/2018 22:55 Colloid - FFP/Plasma 300.0
11/24/2018 23:55 Colloid - FFP/Plasma 600.0
11/25/2018 00:10 Colloid - Platelets 200.0

Appendix B

RUN DATE: 25/18 [redacted] [redacted] *LIVE PAGE 1
RUN TIME: 1941 Blood Bank Tests Data
RUN USER: [redacted]

[redacted] - 24/F DOB [redacted] ADM IN F.SICU F.1380/A
162.56 cm 58.967 kg 1.63 m2 22.3 kg/m2 Unit No: [redacted] /Acct No: [redacted]
Resuscitation Status: DNR/Allow Natural Death
Allergies/ADRs: No Known Drug Allergies
* More Data May Exist Than is Printed *

Blood Product Summary | Blood Bank Tests | Transfusion History

	Nov 24,18 23:09
Blood Type	O NEG
Antibody Screen	NEGATIVE
Crossmatch IS Only	Resulted
BBK History Checked	See Hx

[redacted] 11/25/18

RUN DATE: 26/18 [redacted] [redacted] *LIVE PAGE 1
RUN TIME: 1420 Blood Bank Tests Data
RUN USER: [redacted]

[redacted] - 24/F DOB [redacted] ADM IN F.SICU F.1380/A
162.56 cm 58.967 kg 1.63 m2 22.3 kg/m2 Unit No:[redacted]/Acct No:[redacted]
Resuscitation Status: Full Code
Allergies/ADRs: No Known Drug Allergies
* More Data May Exist Than is Printed *

Collection: Nov 25,18 at 19:50	Ba[redacted]	
Specimen Inquiry		
Blood Type	O NEG	
Antibody Screen	NEGATIVE	
Crossmatch Immediate Spin Only	Complete	
BBK History Checked	YES NO PREV RXN	

[redacted]

VRL | Eurofins Pre-Transplant Testing

[redacted]

****
* FINAL *
* *
****

Requesting Facility: [redacted]

Accession Nbr: [redacted]
Date Received: 11/26/2018 04:20
Date Of Final Report: 11/26/2018 13:49
Date Report Generated: 11/26/2018 13:49
Gender: UNKNOWN Date Of Birth: UNKNOWN

Donor ID-1: [redacted]
Donor ID-2: [redacted]
Donor ID-3: [redacted]
Donor ID-4:

Tube Type	Collection Date/Time	Refrigeration Date/Time	Centrifugation Date/Time	Transfusion Status	Sample Type
RED	11/25/2018 19:00	11/25/2018 19:15		POST	PRE MORTEM
EDTA	11/25/2018 19:00	11/25/2018 19:15		POST	PRE MORTEM

TEST REQUESTED	RESULTS	REFERENCE RANGE
RPR (Non-treponemal syphilis) (Completed: 11/26/2018 07:48)	NON-REACTIVE	NON-REACTIVE ASiManager-AT RPR Card Test for Syphilis. FDA-licensed test for cadaveric- and living-donor screening.
ABO/Rh (Completed: 11/26/2018 07:13)	INDETERMINATE	Ortho-Clinical ID-MTS Gel Test

Comments: FORWARD AND REVERSE BLOOD TYPES ARE DISCREPANT
FORWARD TYPE IS O NEGATIVE REVERSE IS A

HIV-1/HCV/HBV NAT (Ultrio) (Completed: 11/26/2018 13:36)	NON-REACTIVE	NON-REACTIVE Gen-Probe Procleix Ultrio TMA Assay FDA-licensed test for cadaveric- and living-donor screening.
EB VCA IgG (Completed: 11/26/2018 07:50)	** POSITIVE	NEGATIVE Bio-Rad EB VCA IgG EIA
Toxoplasma IgG (Completed: 11/26/2018 07:50)	NEGATIVE	NEGATIVE Bio-Rad Toxoplasma IgG EIA
EB VCA IgM (Completed: 11/26/2018 07:51)	NEGATIVE	NEGATIVE Bio-Rad EB VCA IgM EIA

**** END OF REPORT ****

CLIA # [redacted]
FDA # [redacted]

Laboratory Director: [redacted]

P. 3

VRL | Eurofins Pre-Transplant Testing

[redacted]

****
* FINAL *
*
****

Requesting Facility: [redacted]

Accession Nbr: [redacted]
Date Received: 11/26/2018 04:20
Date Of Final Report: 11/26/2018 13:49
Date Report Generated: 11/26/2018 13:49
Gender: UNKNOWN Date Of Birth: UNKNOWN

Donor ID-1: [redacted]
Donor ID-2: [redacted]
Donor ID-3: [redacted]
Donor ID-4:

Tube Type	Collection Date/Time	Refrigeration Date/Time	Centrifugation Date/Time	Transfusion Status	Sample Type
EDTA	11/25/2018 19:05	11/25/2018 19:15		POST	PRE MORTEM

TEST REQUESTED	RESULTS	REFERENCE RANGE
ABO/Rh (Completed: 11/26/2018 07:12)	INDETERMINATE	Ortho-Clinical ID-MTS Gel Test

Comments: FORWARD AND REVERSE BLOOD TYPES ARE DISCREPANT
FORWARD TYPE IS O NEGATIVE AND REVERSE IS A

**** END OF REPORT ****

CLIA # [redacted]
FDA # [redacted]

Laboratory Director: [redacted]

[redacted]

Donor ID [redacted]
UNOS ID AFKY198
Tissue ID [redacted]

Donor Demographics:
[redacted]
DOB [redacted]
H/W- 66 inches / 129.9 lbs

Case Summary:
24 year old female 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.

Transfusion History:

Transfusion Location	Transfusion Date /Time	Product Given	Product Blood Type
ED	11/24/18 2140	Platelets 299 ml	A positive
ED	11/24/18 2140	Platelets 306 ml	O negative
ED	11/24/18 2140	Platelets 307 ml	O negative
ED	11/24/18 2140	Platelets 199 ml	A positive
ED	11/24/15 2140	FFP 350 ml	O negative
ED	11/24/15 2140	FFP 350 ml	O negative
ED	11/24/15 2140	FFP 350 ml	O negative
ED	11/24/18 2140	FFP 350 ml	A positive
ED	11/24/18 2140	FFP 350 ml	A positive
ED	11/24/18 2140	FFP 350 ml	A positive
ED	11/24/18 2140	FFP 350 ml	O negative
ED	11/24/18 2140	FFP 350 ml	A positive
ED	11/24/18 2140	Cryo 125ml	O positive
SI	11/24/18 2220	Pack Cells 250 ml	O negative
SI	11/24/18 2220	Pack Cells 250 ml	O negative
SI	11/24/18 2220	Pack Cells 250 ml	O negative

[redacted]

SI	11/24/18 2220	Pack Cells 250 ml	O negative
SI	11/24/18 2220	Pack Cells 250 ml	O negative
SI	11/24/18 2220	Pack Cells 250 ml	O negative
SI	11/24/18 2220	Pack Cells 250 ml	O negative
SI	11/24/18 2220	Pack Cells 250 ml	O negative
SI	11/24/18 2220	Pack Cells 250 ml	O negative
SI	11/24/18 2220	Pack Cells 250 ml	O negative
SI	11/24/18 2220	FFP 350 ml	A negative
SI	11/24/18 2220	FFP 350 ml	A negative
ABO #1 Collection Date/ Time 11/24/18 2309- O negative total volume of blood products given: 7236 ml			
SICU	11/25/18 0440	Pack Cells 250 ml	O negative
SICU	11/25/18 0440	Pack Cells 250 ml	O negative
ABO #2 Collection Date /Time 11/25/18 1950- O negative total volume of blood products given: 500 ml			
ABO # 3 Collection Date/Time 11/27/18 0400- A negative total volume of blood products given: 7736 ml			

Total Products Given:

ED

Platelets 4 units total volume -1111 ml
FFP 8 units total volume- 2800 ml
Cryo- 1 vial – total volume- 125 ml

SI

FFP 2 units total volume- 700 ml
PRBC 10 units total volume- 2500 ml

SICU

PRBC 2 units total volume- 500 ml

ABO Draw times

ABO #1 11/24/18 2309
ABO #2 11/25/18 1950
ABO #3 post recovery 11/27/18 0400

Donor ID AFKY198 [redacted]

[redacted] Donor Hospital [redacted]

LABORATORY RESULTS

PATIENT: [redacted] ACCT #: [redacted] LOC: F.PACUA U #: [redacted]
AGE/SX: 24/F ROOM: F.1163 REG: 11/24/18
REG DR: [redacted] MD DOB: [redacted] BED: A DIS: 11/27/18
STATUS: DIS INx

Specimen: 1124:QV:BB00030S Collected: 11/24/18-2309 Status: COMP Req#: [redacted]
Received: 11/24/18-2320 Subm Dr: [redacted] MD

Ordered: CRYO POOLED, FFP < 24 E2555/10, PC LEUKOREDUCED/12, PLTPHLR/4, TS, CROSSMATCH IS/12
Comments: PLEASE REDRAW--ERRONEOUS (2243) CNH
Anticipated Need: Hold
Anticipated Need: When Available
Hgb after 1st unit: No

PCLR
W204218785210 O NEG PCLR PRSMD TRFSD 11/24/18 2220 FLAB.[redacted]
** *EMERGENCY ISSUED* **
DID YOU PERFORM A VISUAL CHECK ON THE UNIT? *Y*
DID YOU ENTER THE NAME OF THE MESSENGER? *Y*
Location of Patient When Blood Issued? *SI*
Issuing to Monitored System? *None*
Volume: *250* ML TX Begin: *11/24/18-2220* By *AutoDft*
TX End: *11/24/18-2220* By *AutoDft*

PCLR
W200218555270 O NEG PCLR PRSMD TRFSD 11/24/18 2220 FLAB.[redacted]
** *EMERGENCY ISSUED* **
DID YOU PERFORM A VISUAL CHECK ON THE UNIT? *Y*
DID YOU ENTER THE NAME OF THE MESSENGER? *Y*
Location of Patient When Blood Issued? *SI*
Issuing to Monitored System? *None*
Volume: *250* ML TX Begin: *11/24/18-2220* By *AutoDft*
TX End: *11/24/18-2220* By *AutoDft*

W200918055187 O NEG PCLR PRSMD TRFSD 11/24/18 2220 FLAB.[redacted]
** *EMERGENCY ISSUED* **
DID YOU PERFORM A VISUAL CHECK ON THE UNIT? *Y*
DID YOU ENTER THE NAME OF THE MESSENGER? *Y*
Location of Patient When Blood Issued? *SI*
Issuing to Monitored System? *None*
Volume: *250* ML TX Begin: *11/24/18-2220* By *AutoDft*
TX End: *11/24/18-2220* By *AutoDft*

W201718426868 O NEG PCLR PRSMD TRFSD 11/24/18 2220 FLAB.[redacted]
** *EMERGENCY ISSUED* **
DID YOU PERFORM A VISUAL CHECK ON THE UNIT? *Y*
DID YOU ENTER THE NAME OF THE MESSENGER? *Y*
Location of Patient When Blood Issued? *SI*
Issuing to Monitored System? *None*
Volume: *250* ML TX Begin: *11/24/18-2220* By *AutoDft*
TX End: *11/24/18-2220* By *AutoDft*

W203618668905 O NEG PCLR PRSMD TRFSD 11/24/18 2220 FLAB.[redacted]

** CONTINUED ON NEXT PAGE **

[redacted] Donor Hospital [redacted]

[redacted]

LABORATORY RESULTS

PATIENT: [redacted] ACCESSION #:

Specimen: 1124:QV:BB00030S Collected: 11/24/18-2309 (Continued)

** *EMERGENCY ISSUED* **
DID YOU PERFORM A VISUAL CHECK ON THE UNIT? Y
DID YOU ENTER THE NAME OF THE MESSENGER? Y
Location of Patient When Blood Issued? *SI*
Issuing to Monitored System? *None*
Volume: *250* ML TX Begin: *11/24/18-2220* By *AutoDft*
TX End: *11/24/18-2220* By *AutoDft*
W204918375021 O NEG PCLR TRANSFUSED 11/25/18 0440 FLAB.[redacted]
DID YOU PERFORM A VISUAL CHECK ON THE UNIT? Y
DID YOU ENTER THE NAME OF THE MESSENGER? Y
Location of Patient When Blood Issued? *SICU*
Issuing to Monitored System? *None*
Volume: *250* ML TX Begin: *11/25/18-0451* By *FNUR.*[redacted]
TX End: *11/25/18-0558* By *FNUR.*[redacted]
PCLR E0685
W201718435862 O NEG PCLR E0685 PRSMD TRFSD 11/24/18 2220 FLAB.[redacted]
** *EMERGENCY ISSUED* **
DID YOU PERFORM A VISUAL CHECK ON THE UNIT? Y
DID YOU ENTER THE NAME OF THE MESSENGER? Y
Location of Patient When Blood Issued? *SI*
Issuing to Monitored System? *None*
Volume: *250* ML TX Begin: *11/24/18-2220* By *AutoDft*
TX End: *11/24/18-2220* By *AutoDft*
PCLR E0686
W201718432629 O NEG PCLR E0686 PRSMD TRFSD 11/24/18 2220 FLAB.[redacted]
** *EMERGENCY ISSUED* **
DID YOU PERFORM A VISUAL CHECK ON THE UNIT? Y
DID YOU ENTER THE NAME OF THE MESSENGER? Y
Location of Patient When Blood Issued? *SI*
Issuing to Monitored System? *None*
Volume: *250* ML TX Begin: *11/24/18-2220* By *AutoDft*
TX End: *11/24/18-2220* By *AutoDft*
W201718435095 O NEG PCLR E0686 PRSMD TRFSD 11/24/18 2220 FLAB.[redacted]
** *EMERGENCY ISSUED* **
DID YOU PERFORM A VISUAL CHECK ON THE UNIT? Y
DID YOU ENTER THE NAME OF THE MESSENGER? Y
Location of Patient When Blood Issued? *SI*
Issuing to Monitored System? *None*
Volume: *250* ML TX Begin: *11/24/18-2220* By *AutoDft*
TX End: *11/24/18-2220* By *AutoDft*
W201718438902 O NEG PCLR E0686 PRSMD TRFSD 11/24/18 2220 FLAB.[redacted]
** *EMERGENCY ISSUED* **
DID YOU PERFORM A VISUAL CHECK ON THE UNIT? Y
DID YOU ENTER THE NAME OF THE MESSENGER? Y

** CONTINUED ON NEXT PAGE **

[redacted] 4/F Acct#: [redacted] Loc: F.PACUA [redacted]
DOB: [redacted] Unit#: [redacted]

Donor ID: AFKY198 [redacted]

[redacted] Donor Hospital [redacted]

LABORATORY RESULTS

PATIENT: [redacted] **ACCESSION #:**

Specimen: 1124:QV:BB00030S **Collected:** 11/24/18-2309 (Continued)

Location of Patient When Blood Issued? *SI*
Issuing to Monitored System? *None*
Volume: *250* ML TX Begin: *11/24/18-2220* By *AutoDft*
TX End: *11/24/18-2220* By *AutoDft*
W201718440102 O NEG PCLR E0686 TRANSFUSED 11/25/18 0440 FLAB.[redacted]
DID YOU PERFORM A VISUAL CHECK ON THE UNIT? *Y*
DID YOU ENTER THE NAME OF THE MESSENGER? *Y*
Location of Patient When Blood Issued? *SICU*
Issuing to Monitored System? *None*
Volume: *250* ML TX Begin: *11/25/18-0450* By *FNUR.*[redacted]
TX End: *11/25/18-0558* By *FNUR.*[redacted]
W201718448636 O NEG PCLR E0686 PRSMD TRFSD 11/24/18 2220 FLAB.[redacted]
** *EMERGENCY ISSUED* **
DID YOU PERFORM A VISUAL CHECK ON THE UNIT? *Y*
DID YOU ENTER THE NAME OF THE MESSENGER? *Y*
Location of Patient When Blood Issued? *SI*
Issuing to Monitored System? *None*
Volume: *250* ML TX Begin: *11/24/18-2220* By *AutoDft*
TX End: *11/24/18-2220* By *AutoDft*
PLTPH LR E3087
W203618873454 A POS PLTPH LR E3087 PRSMD TRFSD 11/24/18 2140 FLAB.[redacted]
** *EMERGENCY ISSUED* **
DID YOU PERFORM A VISUAL CHECK ON THE UNIT? *Y*
DID YOU ENTER THE NAME OF THE MESSENGER? *Y*
Location of Patient When Blood Issued? *ED*
Issuing to Monitored System? *None*
Volume: *299* ML TX Begin: *11/24/18-2140* By *AutoDft*
TX End: *11/24/18-2140* By *AutoDft*

W203618875490 O NEG PLTPH LR E3087 PRSMD TRFSD 11/24/18 2140 FLAB.[redacted]
** *EMERGENCY ISSUED* **
DID YOU PERFORM A VISUAL CHECK ON THE UNIT? *Y*
DID YOU ENTER THE NAME OF THE MESSENGER? *Y*
Location of Patient When Blood Issued? *ED*
Issuing to Monitored System? *None*
Volume: *306* ML TX Begin: *11/24/18-2140* By *AutoDft*
TX End: *11/24/18-2140* By *AutoDft*
PLTPH LR E3088
W203618875490 O NEG PLTPH LR E3088 PRSMD TRFSD 11/24/18 2140 FLAB.[redacted]
** *EMERGENCY ISSUED* **
DID YOU PERFORM A VISUAL CHECK ON THE UNIT? *Y*
DID YOU ENTER THE NAME OF THE MESSENGER? *Y*
Location of Patient When Blood Issued? *ED*
Issuing to Monitored System? *None*
Volume: *307* ML TX Begin: *11/24/18-2140* By *AutoDft*

** CONTINUED ON NEXT PAGE **

[redacted] 4/F Acct#: [redacted] Loc: F.PACUA [redacted]
DOB: [redacted] Unit#: [redacted]

Donor ID: AFKY198 [redacted]

[redacted] Baptist [redacted]

LABORATORY RESULTS

PATIENT: [redacted] ACCESSION #:

Specimen: 1124:QV:BB00030S Collected: 11/24/18-2309 (Continued)

TX End: *11/24/18-2140* By *AutoDft*
PLTPH LR E3089
W203618873467 A NEG PLTPH LR E3089 TRANSFUSED 11/24/18 2140 FLAB.[redacted]
** *EMERGENCY ISSUED* **
DID YOU PERFORM A VISUAL CHECK ON THE UNIT? Y
DID YOU ENTER THE NAME OF THE MESSENGER? Y
Location of Patient When Blood Issued? *ED*
Issuing to Monitored System? *None*
Volume: *199* ML TX Begin: *11/24/18-2150* By *FRN.RN*
TX End: *11/24/18-2200* By *FRN.RN*
FFP < 24 E2555
W200318267969 A NEG FFP < 24 E2555 PRSMD TRFSD 11/24/18 2220 FLAB.[redacted]
** *EMERGENCY ISSUED* **
DID YOU PERFORM A VISUAL CHECK ON THE UNIT? Y
DID YOU ENTER THE NAME OF THE MESSENGER? Y
Location of Patient When Blood Issued? *SI*
Issuing to Monitored System? *None*
Volume: *350* ML TX Begin: *11/24/18-2220* By *AutoDft*
TX End: *11/24/18-2220* By *AutoDft*

W201218627990 A NEG FFP < 24 E2555 PRSMD TRFSD 11/24/18 2220 FLAB.[redacted]
** *EMERGENCY ISSUED* **
DID YOU PERFORM A VISUAL CHECK ON THE UNIT? Y
DID YOU ENTER THE NAME OF THE MESSENGER? Y
Location of Patient When Blood Issued? *SI*
Issuing to Monitored System? *None*
Volume: *350* ML TX Begin: *11/24/18-2220* By *AutoDft*
TX End: *11/24/18-2220* By *AutoDft*

W201218655567 O NEG FFP < 24 E2555 PRSMD TRFSD 11/24/18 2140 FLAB.[redacted]
** *EMERGENCY ISSUED* **
DID YOU PERFORM A VISUAL CHECK ON THE UNIT? Y
DID YOU ENTER THE NAME OF THE MESSENGER? Y
Location of Patient When Blood Issued? *ED*
Issuing to Monitored System? *None*
Volume: *350* ML TX Begin: *11/24/18-2140* By *AutoDft*
TX End: *11/24/18-2140* By *AutoDft*
W201218702813 O NEG FFP < 24 E2555 PRSMD TRFSD 11/24/18 2140 FLAB.[redacted]
** *EMERGENCY ISSUED* **
DID YOU PERFORM A VISUAL CHECK ON THE UNIT? Y
DID YOU ENTER THE NAME OF THE MESSENGER? Y
Location of Patient When Blood Issued? *ED*
Issuing to Monitored System? *None*
Volume: *350* ML TX Begin: *11/24/18-2140* By *AutoDft*
TX End: *11/24/18-2140* By *AutoDft*

** CONTINUED ON NEXT PAGE **

[redacted] 24/F Acct#: [redacted] Loc: F.PACUA [redacted]
DOB: [redacted] Unit#: [redacted]

[redacted]

LABORATORY RESULTS

PATIENT: [redacted] ACCESSION #:

Specimen: 1124:QV:BB00030S Collected: 11/24/18-2309 (Continued)

W201218709512 O NEG FFP < 24 E2555 PRSMD TRFSD 11/24/18 2140 FLAB.[redacted]
** *EMERGENCY ISSUED* **
DID YOU PERFORM A VISUAL CHECK ON THE UNIT? Y
DID YOU ENTER THE NAME OF THE MESSENGER? Y
Location of Patient When Blood Issued? *ED*
Issuing to Monitored System? *None*
Volume: *350* ML TX Begin: *11/24/18-2140* By *AutoDft*
TX End: *11/24/18-2140* By *AutoDft*

W201218722549 A POS FFP < 24 E2555 PRSMD TRFSD 11/24/18 2140 FLAB.[redacted]
** *EMERGENCY ISSUED* **
DID YOU PERFORM A VISUAL CHECK ON THE UNIT? Y
DID YOU ENTER THE NAME OF THE MESSENGER? Y
Location of Patient When Blood Issued? *ED*
Issuing to Monitored System? *None*
Volume: *350* ML TX Begin: *11/24/18-2140* By *AutoDft*
TX End: *11/24/18-2140* By *AutoDft*

W201218732460 A POS FFP < 24 E2555 PRSMD TRFSD 11/24/18 2140 FLAB.[redacted]
** *EMERGENCY ISSUED* **
DID YOU PERFORM A VISUAL CHECK ON THE UNIT? Y
DID YOU ENTER THE NAME OF THE MESSENGER? Y
Location of Patient When Blood Issued? *ED*
Issuing to Monitored System? *None*
Volume: *350* ML TX Begin: *11/24/18-2140* By *AutoDft*
TX End: *11/24/18-2140* By *AutoDft*

W201218732480 A POS FFP < 24 E2555 PRSMD TRFSD 11/24/18 2140 FLAB.[redacted]
** *EMERGENCY ISSUED* **
DID YOU PERFORM A VISUAL CHECK ON THE UNIT? Y
DID YOU ENTER THE NAME OF THE MESSENGER? Y
Location of Patient When Blood Issued? *ED*
Issuing to Monitored System? *None*
Volume: *350* ML TX Begin: *11/24/18-2140* By *AutoDft*
TX End: *11/24/18-2140* By *AutoDft*

W202918019083 O NEG FFP < 24 E2555 PRSMD TRFSD 11/24/18 2140 FLAB.[redacted]
** *EMERGENCY ISSUED* **
DID YOU PERFORM A VISUAL CHECK ON THE UNIT? Y
DID YOU ENTER THE NAME OF THE MESSENGER? Y
Location of Patient When Blood Issued? *ED*
Issuing to Monitored System? *None*
Volume: *350* ML TX Begin: *11/24/18-2140* By *AutoDft*
TX End: *11/24/18-2140* By *AutoDft*

W203218080139 A POS FFP < 24 E2555 PRSMD TRFSD 11/24/18 2140 FLAB.[redacted]
** *EMERGENCY ISSUED* **

** CONTINUED ON NEXT PAGE **

[redacted] 4/F Acct#: [redacted] Loc: F.PACUA [redacted]
DOB: [redacted] Unit#: [redacted]

Donor ID: AFKY198

[redacted]

LABORATORY RESULTS

PATIENT: [redacted] ACCESSION #:

Specimen: 1124:QV:BB00030S Collected: 11/24/18-2309 (Continued)

DID YOU PERFORM A VISUAL CHECK ON THE UNIT? Y
DID YOU ENTER THE NAME OF THE MESSENGER? Y
Location of Patient When Blood Issued? *ED*
Issuing to Monitored System? *None*
Volume: *350* ML TX Begin: *11/24/18-2140* By *AutoDft*
TX End: *11/24/18-2140* By *AutoDft*

CRYO POOLED
W201218982707 O POS CRYO POOLED PRSMD TRFSD 11/24/18 2140 FLAB[redacted]
** *EMERGENCY ISSUED* **
DID YOU PERFORM A VISUAL CHECK ON THE UNIT? Y
DID YOU ENTER THE NAME OF THE MESSENGER? Y
Location of Patient When Blood Issued? *ED*
Issuing to Monitored System? *None*
Volume: *125* ML TX Begin: *11/24/18-2140* By *AutoDft*
TX End: *11/24/18-2140* By *AutoDft*

PREV HIST CK	NO PREVIOUS HISTORY	11/25/18-0055
ABO TYPE		
RH TYPE		
BLOOD TYPE	O NEG	11/25/18-0055
ABSC	NEGATIVE	11/25/18-0055
CROSSMATCH		
PC LEUKOREDUCED	W201718440102 O NEG Comp? Y	11/25/18-0106
PC LEUKOREDUCED	W204918375021 O NEG Comp? Y	11/25/18-0106
PC LEUKOREDUCED	W204218785210 O NEG Comp? Y	11/27/18-1249
PC LEUKOREDUCED	W200218555270 O NEG Comp? Y	11/27/18-1249
PC LEUKOREDUCED	W200918055187 O NEG Comp? Y	11/27/18-1249
PC LEUKOREDUCED	W201718448636 O NEG Comp? Y	11/27/18-1249
PC LEUKOREDUCED	W201718438902 O NEG Comp? Y	11/27/18-1249
PC LEUKOREDUCED	W201718435862 O NEG Comp? Y	11/27/18-1249
PC LEUKOREDUCED	W201718426868 O NEG Comp? Y	11/27/18-1249
PC LEUKOREDUCED	W201718435095 O NEG Comp? Y	11/27/18-1249
PC LEUKOREDUCED	W201718432629 O NEG Comp? Y	11/27/18-1249
PC LEUKOREDUCED	W203618668905 O NEG Comp? Y	11/27/18-1249

** END OF REPORT **

[redacted] 24/F Acct#: [redacted] Loc: F.PACUA [redacted]
DOB: [redacted] Unit#: [redacted]

Donor ID: AFKY198 [redacted]

[redacted] Donor Hospital [redacted]

[redacted]

LABORATORY RESULTS

PATIENT: [redacted] ACCT #: [redacted] LOC: F.PACUA U #: [redacted]
AGE/SX: 24/F ROOM: F.1163 REG: 11/24/18
REG DR: [redacted] MD DOB: [redacted] BED: A DIS: 11/27/18
STATUS: DIS INx

Specimen: 1125:QV:BB00020S Collected: 11/25/18-1950 Status: COMP Req#: 07996439
Received: 11/25/18-2002 Subm Dr: [redacted] MD

Ordered: PC LEUKOREDUCED/2/-1, TS, CROSSMATCH IS/2
PCLR

W203618684513 O NEG PCLR TRANSFUSED 11/26/18 1206 FLAB[redacted]
DID YOU PERFORM A VISUAL CHECK ON THE UNIT? *Y*
DID YOU ENTER THE NAME OF THE MESSENGER? *Y*
Location of Patient When Blood Issued? *SI*
Issuing to Monitored System? *None*
Volume: *250* ML TX Begin: *11/26/18-1215* By *FNUR*[redacted]
TX End: *11/26/18-1327* By *FNUR*[redacted]

PREV HIST CK	YES NO PREV RXN	11/25/18-2120
ABO TYPE		
RH TYPE		
BLOOD TYPE	O NEG	11/25/18-2120
ABSC	NEGATIVE	11/25/18-2120
CROSSMATCH		
PC LEUKOREDUCED	W203618684513 O NEG Comp? Y	11/25/18-2120
PC LEUKOREDUCED	W200118724499 O NEG Comp? Y <N/A>	11/25/18-2120

** END OF REPORT **

[redacted] 24/F Acct#: [redacted] Loc: F.PACUA [redacted]
DOB: [redacted] Unit#: [redacted]

Patient Name: [redacted]
ABO: O
UNOS #: [redacted]
OPO #: [redacted]
[redacted]

TRANSFUSION/INFUSION - HEMODILUTION WORKSHEET

Date-Time sample drawn: 11/25/2018 19:00[redacted] Post-Transfusion

Transfusion of blood products within 48 hrs prior to specimen draw or asystole

Date-Time	Blood Type	Volume
11/24/2018 21:25	Blood Product - RBC	500.0
11/24/2018 21:40	Blood Product - RBC	250.0
11/24/2018 22:14	Blood Product - RBC	250.0
11/24/2018 22:18	Blood Product - RBC	250.0
11/24/2018 22:20	Blood Product - RBC	250.0
11/24/2018 22:22	Blood Product - RBC	250.0
11/24/2018 22:50	Blood Product - RBC	250.0
11/24/2018 23:30	Blood Product - RBC	250.0
11/24/2018 23:40	Blood Product - RBC	250.0
11/25/2018 05:58	Blood Product - RBC	250.0
11/25/2018 05:58	Blood Product - RBC	250.0

Infusion of colloids within 48 hrs prior to specimen draw or asystole

Date-Time	Colloid Type	Volume
11/24/2018 21:50	Colloid - Platelets	400.0
11/24/2018 22:10	Colloid - FFP/Plasma	600.0
11/24/2018 22:22	Colloid - FFP/Plasma	300.0
11/24/2018 22:26	Colloid - FFP/Plasma	300.0
11/24/2018 22:30	Colloid - FFP/Plasma	300.0
11/24/2018 22:35	Colloid - FFP/Plasma	300.0
11/24/2018 22:45	Colloid - Cryoprecipitate	100.0
11/24/2018 22:53	Colloid - FFP/Plasma	300.0
11/24/2018 22:55	Colloid - FFP/Plasma	300.0
11/24/2018 23:55	Colloid - FFP/Plasma	600.0
11/25/2018 00:10	Colloid - Platelets	200.0

Donor weight in kilograms: 58.9 kilograms (129.9 pounds)

ESTIMATED TOTAL PLASMA VOLUME (TPV)

Weight 45 - 100 kg TPV=Donor Wt (kg)	58.9 / 0.025
Male Weight < 45 or > 100 kg TPV =	BSA X 1560
Female Weight < 45 or > 100 kg TPV =	BSA X 1410
TPV =	2356.00 mls

ESTIMATED TOTAL BLOOD VOLUME (TBV)

Weight 45 - 100 kg TBV=Donor Wt (kg)	58.9 / 0.015
Male Weight < 45 or > 100 kg TBV =	BSA X 2740
Female Weight < 45 or > 100 kg TBV =	BSA X 2370
TBV =	3926.67 mls

A: TOTAL VOLUME OF BLOOD TRANSFUSED IN THE LAST 48 HOURS

RBC's (packed cells) =	3000.0 mls
Whole Blood =	-- mls
Other Blood Products =	-- mls
Total of A =	3000.0 mls

B: TOTAL VOLUME OF COLLOIDS INFUSED IN THE LAST 48 HOURS

FFP/Plasma =	3000.0 mls
Platelets =	600.0 mls
Cryoprecipitate =	100.0 mls
Albumin 5% =	-- mls
Albumin 25% (-- mls * 1.4) =	-- mls
Dextran =	-- mls
Other Colloids =	-- mls
Total of B =	3700.0 mls

C: TOTAL VOLUME OF CRYSTALLOIDS INFUSED IN LAST HOUR

Date-Time	Type	Volume	
11/25/2018 18:00	0.9% NaCl	100.0	mls
11/25/2018 18:00	Vaso in NS	12.0	mls
11/25/2018 18:00	levo in NS	28.1	mls
	Total of C =	140.1	mls

D: DETERMINATION OF ELIGIBILITY

1) Is B + C < TPV?			(	3700.0	+	140.1	=	3840.1	)	<	2356.00	? NO
2) Is A + B + C < TBV?	(	3000.0	+	3700.0	+	140.1	=	6840.1	)	<	3926.67	? NO

SAMPLE DOES NOT QUALIFY

Date Generated: 12/17/2018 10:38[redacted] Trans./Inf. Hemo Wksheet Page 1 of 3
Version #: 2018.3.0.402
Staff Completing: [redacted]

Patient Name: [redacted]
ABO: O
[redacted]

UNOS #: [redacted]
OPO #: [redacted]

[redacted]

TRANSFUSION/INFUSION - HEMODILUTION WORKSHEET

Comments: N/A

Patient Name: [redacted]
ABO: O
[redacted]

UNOS #: [redacted]
OPO #: [redacted]

[redacted]

TRANSFUSION/INFUSION - HEMODILUTION WORKSHEET

Date-Time sample drawn: 11/27/2018 04:00 [redacted] Post-Transfusion

Transfusion of blood products within 48 hrs prior to specimen draw or asystole			Infusion of colloids within 48 hrs prior to specimen draw or asystole		
Date-Time	Blood Type	Volume	Date-Time	Colloid Type	Volume
11/25/2018 05:58	Blood Product - RBC	250.0	--/--/---- --:--	-------	--
11/25/2018 05:58	Blood Product - RBC	250.0			
11/26/2018 13:30	Blood Product - RBC	250.0			

Donor weight in kilograms: 58.9 kilograms (129.9 pounds)

ESTIMATED TOTAL PLASMA VOLUME (TPV)		ESTIMATED TOTAL BLOOD VOLUME (TBV)	
Weight 45 - 100 kg TPV=Donor Wt (kg)	58.9 / 0.025	Weight 45 - 100 kg TBV=Donor Wt (kg)	58.9 / 0.015
Male Weight < 45 or > 100 kg TPV =	BSA X 1560	Male Weight < 45 or > 100 kg TBV =	BSA X 2740
Female Weight < 45 or > 100 kg TPV =	BSA X 1410	Female Weight < 45 or > 100 kg TBV =	BSA X 2370
TPV =	2356.00 mls	TBV =	3926.67 mls

A: TOTAL VOLUME OF BLOOD TRANSFUSED IN THE LAST 48 HOURS

RBC's (packed cells) =	750.0 mls
Whole Blood =	-- mls
Other Blood Products =	-- mls
Total of A =	750.0 mls

B: TOTAL VOLUME OF COLLOIDS INFUSED IN THE LAST 48 HOURS

FFP/Plasma =	-- mls
Platelets =	-- mls
Cryoprecipitate =	-- mls
Albumin 5% =	-- mls
Albumin 25% (-- mls * 1.4) =	-- mls
Dextran =	-- mls
Other Colloids =	-- mls
Total of B =	0.0 mls

C: TOTAL VOLUME OF CRYSTALLOIDS INFUSED IN LAST HOUR

Date-Time	Type	Volume	
11/27/2018 03:00	.45NS	150.0	mls
11/27/2018 03:00	Vasopressin	6.0	mls
11/27/2018 03:00	Zosyn	25.0	mls
		Total of C = 181.0	mls

D: DETERMINATION OF ELIGIBILITY

1) Is B + C < TPV?			(	0.0	+	181.0	=	181.0	)	<	2356.00	? YES
2) Is A + B + C < TBV?	(	750.0	+	0.0	+	181.0	=	931.0	)	<	3926.67	? YES

SAMPLE QUALIFIES

Comments:
Repeated to coincide with blood drawn per tissue request

Appendix C

Donor ABO Audit Log

Donor ID: AFKY198

Blood Type	Entered By	Entered On	Verified By	Verified On
O	[redacted]	11/26/2018 14:29:59	[redacted]	11/26/2018 15:00:51

Generated at 11/30/2018 12:23:07

Close Print

HIGH RISK DISCLOSURE

OPTN ID [redacted] Donor ID [redacted]

This donor meets one or more of the PHS criteria outlined below as determined by the medical/social history, physical examination, and/or laboratory evaluation & has been identified as being at increased risk for recent HIV, HBV, or HCV infection. The risk factors that apply to this donor are checked below. *Source: The PHS Guideline for Reducing Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), & Hepatitis C Virus (HCV) through Organ Transplantation (2013).*

PHS High Risk Factors for Recent HIV, HBV, or HCV Infection:

1	☐	People who have had sex with a person known or suspected to have HIV, HBV, or HCV infection in the preceding 12 months.
2	☐	Men who have had sex with men (MSM) in the preceding 12 months.
3	☐	Women who have had sex with a man with a history of MSM behavior in the preceding 12 months.
4	☐	People who have had sex in exchange for money or drugs in the preceding 12 months.
5	☐	People who have had sex with a person who had sex in exchange for money or drugs in the preceding 12 months.
6	☐	People who have had sex with a person who injected drugs by intravenous, intramuscular, or subcutaneous route for nonmedical reasons in the preceding 12 months.
7	☐	A child who is ≤ 18 months of age and born to a mother known to be infected with, or at increased risk for, HIV, HBV, or HCV infection.
8	☐	A child who has been breastfed within the preceding 12 months and the mother is known to be infected with, or at increased risk for, HIV infection.
9	☐	People who have injected drugs by intravenous, intramuscular, or subcutaneous route for non-medical reasons in the preceding 12 months.
10	☐	People who have been in lockup, jail, prison, or a juvenile correctional facility for more than 72 consecutive hours in the preceding 12 months.
11	☐	People who have been newly diagnosed with, or have been treated for, syphilis, gonorrhea, Chlamydia, or genital ulcers in the preceding 12 months.

PHS High Risk Factors for Recent HCV Infection Only:

12	☐	People who have been on hemodialysis in the preceding 12 months.

PHS High Risk Factors for Disease Transmission:

13	☐	A medical/behavioral history could not be obtained or risk factors could not be determined.
14	☑	A hemodiluted specimen was used for serological testing and the donor's risk for infection is unknown. The following tests were completed using hemodiluted specimens:

This form has been reviewed with AOC [redacted] Date 11/25/18 Time 2045

by Nurse Clinician: [redacted]

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

This form has been reviewed by the representative of the accepting transplant center or designee:

TX Center	Contact Name (print)	Signature	Title	Date	Time
TXC 1	[redacted]	[redacted]	[redacted]	11-27-18	0700
TXC 3	[redacted]	[redacted]	[redacted]	11-27-18	0748
TXC 2	[redacted]	[redacted]	[redacted]	11-27-18	0755

The NC will sign the form that contains signatures from all centers on-site to recover. The CAT will sign the form that contains signatures from all other centers.

[redacted] Staff Signature [redacted] Date 11/25/2018 Time 0755

O 3.033-1 High Risk Disclosure, Rev 14
IMP. 02/10/17

OPTN ID [redacted] Donor ID [redacted]

CAT ABO VERIFICATION

1	ABO 1 received?	☒Yes ☐No
2	Document the ABO 1 as it appears on the test result.	O-
3	ABO 2 received?	☒Yes ☐No
4	Document the ABO 2 as it appears on the test result.	O-
5	Verify the donor name or UNOS # is correct on each ABO test result.	☒Yes ☐No
6	Are both specimens from different draw times?	☒Yes ☐No
7	Was subtyping done for all ABO A and AB blood types? If YES, answer questions 7a-7e. If NO, leave questions 7a-7e blank and explain in comments section.	☐Yes ☐No ☒N/A
7a	If ABO is A or AB, were subtypes done on both specimens?	☐Yes ☐No
7b	Enter the subtypes for each ABO.	ABO1 ABO2
7c	Do the subtypes match?	☐Yes ☐No
7d	If ABO is A or AB, are both separate specimens pre-transfusion samples? (*no red blood cells administered for 120 days prior to collection*). Verify with Nurse Clinician.	☐Yes ☐No
7e	Are both specimens from different draw times?	☐Yes ☐No

If any of questions 7a-7e above are answered NO, enter the ABO and not the subtype into DonorNet.
If subtypes were not used for allocation, document the reason in the comments field below.

Do ABO blood types match?	☒Yes ☐No
Are all ABO test results faxed into DonorNet as viewable attachments?	☒Yes ☐No

[redacted]

Comments: ☐N/A Due to indeterminant results from VRL, a second type ABO was ordered.

Staff Completing: [redacted] Date: 11/26/18 Time: 14:27

O 1.110-5 CAT ABO Verification, Rev 4
REV. 04/12/18

Appendix D

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

1) **Policy.**
   a) It is [redacted] 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 can be given for at least 120 days prior to the sample draw 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.

PROOF

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	Initiate ***O 1.110-6 Blood Draw for Deceased Donors*** to have appropriate samples drawn. 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 or Designee	2	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.

Copy

CDC CDS	3	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***.

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, [redacted] will be used for courier services. • Call the Customer Center to arrange transportation with [redacted]. • 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 [redacted] Resources*** for further details about [redacted] courier services.

c) [redacted] 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)	Hepatitis C RNA (genetic material of virus)	HIV-1/HCV/HBV NAT (Ultrio)

Organ Recovery Services Manual

HepB NAT (HepB RNA)		
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) [redacted] 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.

a) 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 [redacted] Communication Center of any positive results if a mutual organ/tissue donor.
[redacted] 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***.

b) ABO Testing.

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.

c) ABO Verifications.

i) [redacted] 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, notify the AOC/Designee immediately for guidance. If there is an ABO discrepancy, the cause will be investigated and new samples may need to be obtained, repeating the testing and verification process. • If there are conflicting subtype results, the subtype results must not be reported to the OPTN Contractor and the deceased donor must be allocated based on the primary blood type. • Determine if specimens 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 (life-span of red blood cells). History of red blood cell transfusions should be determined by reviewing the patient's hospital medical record, blood bank record, and DRAI. Communicate this review with the CAT. • 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.

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.

Property of

[redacted]

OPTN ID _____ Donor ID _____

CAT ABO VERIFICATION

1	ABO 1 received?	☐Yes ☐No
2	Document the ABO 1 as it appears on the test result.	
3	ABO 2 received?	☐Yes ☐No
4	Document the ABO 2 as it appears on the test result.	
5	Verify the donor name or UNOS # is correct on each ABO test result.	☐Yes ☐No
6	Are both specimens from different draw times?	☐Yes ☐No
7	Was subtyping done for all ABO A and AB blood types? If YES, answer questions 7a-7e. If NO, leave questions 7a-7e blank and explain in comments section.	☐Yes ☐No ☐N/A
7a	If ABO is A or AB, were subtypes done on both specimens?	☐Yes ☐No
7b	Enter the subtypes for each ABO.	ABO1 ABO2
7c	Do the subtypes match?	☐Yes ☐No
7d	If ABO is A or AB, are both separate specimens pre-transfusion samples? (*no red blood cells administered for 120 days prior to collection*). Verify with Nurse Clinician.	☐Yes ☐No
7e	Are both specimens from different draw times?	☐Yes ☐No

If any of questions 7a-7e above are answered NO, enter the ABO and not the subtype into DonorNet.
If subtypes were not used for allocation, document the reason in the comments field below.

Do ABO blood types match?	☐Yes ☐No
Are all ABO test results faxed into DonorNet as viewable attachments?	☐Yes ☐No

Proper

A or AB (pre-transfusion sample)

- A(1) negative = A1
- A(1) positive = A1
- A(non-1) POS = A2
  A(non-1) NEG = A2

Comments: ☐N/A _____

_____

Staff Completing:_____ Date: _____ Time: _____

O 1.110-5 CAT ABO Verification, Rev 4
REV. 04/12/18

[redacted]	Standard Operating Procedure **Organ Recovery Services Manual**	Document Number	O 3.031
		Revision Number	12
	Organ Allocation	Revision Date	06/14/18
		Page 1 of 5	

1) Policy.

a) The purpose of this document is to:

i) Describe the procedure for using the PTR match run for allocating donated organs.

ii) Describe the procedures used to assign identification numbers to a donor.

iii) Describe the procedure followed when an organ is recovered and the recipient then becomes unavailable for the transplant.

iv) Define how [redacted] participates in the mandatory sharing of kidneys for zero antigen mismatched and high CPRA recipients.

v) Define how [redacted] will proceed with organ allocation during regional or national emergency situations.

2) Definitions and/or Acronyms.

Term	Definition
ABO	The system used to identify specific blood groups: A, B, O, or AB.
AOC	Administrator On Call.
AOPO	Association of Organ Procurement Organizations.
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.
Donor ID	Unique identifier assigned by the OPO.
EMR	Electronic Medical Record.
FSC	Family Support Counselor.
HLA	Human Leukocyte Antigens: Group of antigens used in histocompatibility testing to determine match potential between a donor and recipient.
LCAT	Lead Clinical Allocation Technician.
OPTN	Organ Procurement and Transplantation Network.
OPTN ID	A unique identification assigned by the OPTN when an organ donor is registered in DonorNet. (Also known as UNOS ID, UNOS#, or OPTN#)
PTR Match Run	Potential Transplant Recipient Match Run: A computerized algorithm used to prioritize candidates waiting for organs.
UNOS	United Network for Organ Sharing.
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 AOC/Designee, FSC, CDC, CDS, and CAT.

Position	Responsibility
AOC/Designee	Generate a Donor ID within the EMR once authorization has been obtained and ensure a PTR match run is generated for each organ to be allocated.
CDS/CDC AOC/Designee	Maintain communication and provide documentation to the CAT of all information needed for organ placement and data entry into the EMR and/or DonorNet.
CAT	Obtain all information required for the allocation of each organ from the CDC/CDS and communicate that data to the Transplant Centers.

4) Materials and/or Equipment.

a) Access to a computer with internet service, email, and scanner/printer.
b) Access to DonorNet and the EMR.
c) Fax machine.
d) Phone.

5) Procedure.

a) Assignment of the Donor ID.

Responsible Person	Step	Action
AOC/Designee	1	When the FSC completes the authorization process, generate a Donor ID within the EMR.
All staff	2	The Donor ID is documented where indicated on any [redacted] document and is recorded on all documents related to the donation process in the donor record.

b) Registering the Authorized Donor into DonorNet.

Responsible Person	Step	Action
AOC/Designee	1	Enter data into DonorNet to begin the initial registration of the authorized donor into the OPTN DonorNet database.
All staff	2	The OPTN ID is assigned by DonorNet at the time the potential donor is entered into the database. The OPTN ID must be documented as indicated in the organ donor record on every document that is used in the organ donation process.
AOC/Designee	3	Verify the ABO in DonorNet IAW ***O 1.110 Specimens Drawn for Donor Evaluation.***

c) Double Kidney Allocation.
i) [redacted] will offer kidneys individually through one of the allocation sequences in the applicable OPTN policies before offering both kidneys to a single candidate (unless reported to UNOS prior to allocation that the deceased donor meets applicable criteria).

Responsible Person	Step	Action
AOC/Designee	1	Determine if the donor meets criteria for Double Kidney Allocation IAW OPTN policy before the kidney PTR match run is generated.
CAT/Designee	2	If the donor meets Double Kidney Allocation criteria, ensure that the kidney match run is generated as such.

d) Reporting and Verifying HLA Results.
i) [redacted] utilizes a 2-person verification process to verify the documentation of HLA results.

Responsible Person	Step	Action
HLA Lab	1	HLA results are entered into DonorNet and sent to the CAT once testing is complete.
CAT/Designee	2	Once the HLA results are received from the HLA Lab, compare the HLA report to the HLA results in DonorNet. Verify the results are correctly entered. • If the results are the same, document in the EMR on *Referral> Organ Donor Task Checklist* that the HLA testing results have been verified. • If the results are not the same, contact HLA staff for confirmation and/or correction of the test results and notify the AOC/Designee.

e) Generating a PTR Match Run for Each Organ.

Responsible Person	Step	Action
CAT/Designee	1	A PTR match run will be generated for each organ to be allocated once all required data has been entered in DonorNet.

CAT/Designee	1	• ABO verification must be completed IAW ***O 1.110 Specimens Drawn for Donor Evaluation*** PRIOR to generating a PTR match run. • This may also include HLA and serological testing results.

f) Organ Offers.

Responsible Person	Step	Action
CAT/Designee	1	Once all required donor information (IAW applicable OPTN Policy) has been entered into the EMR and uploaded to DonorNet, and at the discretion of the AOC/Designee, make offers for each authorized organ, utilizing the appropriate PTR match run. • Directed Donation Exception: For cases of directed donation, [redacted] staff will contact the recipient transplant center(s). If the directed donation is not possible, the organ will be allocated according to the PTR match run. • Military Donor Exception: If the donor was an active member of any branch of the military at the time of their death, all authorized organs are offered to the Walter Reed National Military Medical Center per Department of Defense directive. Any organs not accepted by the military are then offered according to the PTR match run.
CAT/Designee	2	Electronic offers will be sent via DonorNet. All offers will be monitored continuously for transplant center offer status. • Verbal offers will be made to centers that are unable to be notified electronically.
CAT/Designee	3	Provide additional information to transplant centers as offers are reviewed. Contact the CDC or AOC/Designee as needed for further information. If a center requests to speak with the onsite CDC, forward their contact information to the CDC.
CAT/Designee	4	If a transplant center requests a delay, waivers, or any further testing, consult the AOC/Designee.
CAT/Designee	5	Enter the appropriate DonorNet code for the offer outcome, if needed to move to the next transplant center.
CAT/Designee	6	Send additional electronic organ offers as required on DonorNet until organ placement is complete.
CAT/Designee	7	If an extra-renal organ allocated is going to be split, as in the case of a liver or lung, placement attempts will be made to allocate the subsequent remaining segment or lobe up until the time the OR is set.
CAT/Designee	8	Backup offers will be sent for each organ. Backup centers who have accepted an offer will be updated on donor status changes and organ dispositions promptly as they occur.
CAT/Designee	9	If there are conditions or waivers on the accepting offer, they must be documented in the EMR *Case Notes*. The AOC/Designee must pre-approve all waivers or conditions of accepting an organ by a transplant center.
[redacted] policy	10	Primary transplant programs will be given the option to recover the organ(s) being accepted.
CAT/Designee	11	With the exception of zero mismatched kidneys and kidneys shared nationally for high CPRA candidates, the UNOS Organ Center must be contacted to assist with national placement of kidneys.

g) Deviation from the PTR Match Run.

Responsible Person	Step	Action
AOC/Designee	1	Any recipient/transplant center may be bypassed on the PTR match run but must be justified. Reasons may include, but are not limited to: • Accepted directed donation. • A sub-optimal donation.

AOC/Designee	1	• Time constraints imposed by families, coroner, local donor site, or a local transplant center urgent need. • The alternative is that the organ(s) would not be recovered at all.
CAT/Designee	2	Document the reason(s) for the PTR match run deviation in the EMR *Case Notes* with as much detail as possible and notify the LCAT.
CAT/Designee	3	Expedited offers may be made at the discretion of the AOC/Designee. Once the offer is made and the transplant center has accepted, the intended recipient must be on the PTR match run. • Enter the bypass code into DonorNet for all recipients between the last electronic offer made and to the accepting transplant centers recipient. • The reasons for the deviation will be listed in the bypass code reason box.
CAT/Designee	4	If a center requests local back up for an organ and cold ischemic time is a consideration, the AOC/Designee may grant the center permission for local back up. • Document this permission in the EMR *Case Notes*. • The organ will be indicated as accepted for the recipient offered at the time of the offer on the PTR match run.
CAT/Designee	5	If an organ is recovered for a recipient that becomes unavailable, notify the AOC/Designee for direction to do one of the following: • Place the organ in accordance with the order of the PTR match run. • Allow the center in possession of the organ to use local backup. • Determine an alternative that would be in the best interest for the use of the organ.

h) Re-execution of a PTR Match Run.

Responsible Person	Step	Action
CAT/Designee	1	A PTR match run will only be re-generated at the discretion and permission of the AOC/Designee and in accordance with OPTN policy. • Documentation for re-generating a PTR match run will be noted in the EMR *Case Notes*.

i) Post-Recovery Kidney Reallocation.

i) Kidneys will be reallocated after recovery when accepting transplant center(s) decline the organ(s) post-recovery due to recipient issues, unacceptable pump numbers, poor biopsy results, etc.

Responsible Person	Step	Action
CAT/Designee	1	Reallocate the kidney(s) while the CDS is still involved in recovery operations or traveling. Pass the reallocation duties to the CDS once available.
CDS	2	Perform post-recovery kidney allocation IAW ***O 3.031-1 Post-Recovery Kidney Reallocation***.

j) Research Organ Placement.

i) Authorized organs that are not utilized for transplant will be offered for research IAW ***L 22.000 Procuring Tissues and Organs for Research Purposes***.

k) Organ Allocation During Emergency Situations.

Responsible Person	Step	Action
[redacted] policy	1	Transportation Disruption: • If communications are uninterrupted, but transportation of the organs is either not possible or severely impaired, [redacted] will contact UNOS to determine proper operating procedures.

[redacted] Policy	2	Communication Disruption: • In the event of an internet outage, [redacted] will contact UNOS by phone to determine proper operating procedures. • In the event of a telecommunications (land/mobile phone) outage, [redacted] will contact UNOS via e-mail to determine proper operating procedures and obtain assistance. • The PTR match run system will continue to be used for organ allocation.
Chief Clinical Officer/ Designee	3	Variations from normal operating procedures due to an outage will be documented and submitted to the UNOS Policy Compliance Department.

6) Attachments.

a) O 3.031-1 Post-Recovery Kidney Reallocation.

7) Referenced and Related Procedures.

a) O 1.110 Specimens Drawn for Donor Evaluation.

8) Standards and Regulations.

a) AOPO Standard CL 5 and CL 5.1.

b) Centers for Medicare and Medicaid Services (CMS); CMS 42 CFR Chapter IV § 486.344 (g) Evaluation and management of potential donors and organ placement and recovery.

c) Department of Defense Directives 6465.3.

d) OPTN Policies:

i) Policy 1: Administrative Rules and Definitions.
ii) Policy 2: Deceased Donor Organ Procurement.
iii) Policy 4: Histocompatibility.
iv) Policy 5: Organ Offers, Acceptance, and Verification.
v) Policy 6: Allocation of Heart and Heart-Lungs.
vi) Policy 7: Allocation of Intestines.
vii) Policy 8: Allocation of Kidneys.
viii) Policy 9: Allocation of Livers and Liver-Intestines.
ix) Policy 10: Allocation of Lungs.
x) Policy 11: Allocation of Pancreas, Kidney-Pancreas, and Islets.

Property of

[redacted]	Standard Operating Procedure **Organ Recovery Services Manual**	Document Number	O 3.033
		Revision Number	15
	Communication of Increased Risk Factors	Revision Date	06/14/18
		Page 1 of 2	

1) Policy.

a) The purpose of this document is to provide instruction for communicating any known increased risk factors to transplant centers receiving organs.

2) Definitions and/or Acronyms.

Term	Definition
AOC	Administrator On Call.
CAT	Clinical Allocation Technician.
CDC	Clinical Donation Coordinator.
DonorNet	The web-based, donor and recipient database used by the OPTN contractor.
EMR	Electronic Medical Record.
OPTN	Organ Procurement Transplant Network.
PHS	United States Public Health Service.
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 AOC, CDC, and CAT.

Position	Responsibility
CDC	• Review with the AOC/Designee and CAT all information regarding the donor's medical, social, and sexual history as well as any known conditions that may be transmitted by the donor organ. • Execute ***O 3.033-1 Increased Risk Disclosure*** and ensure it is completed by those onsite representatives from each accepting transplant center prior to transplant.
CAT/Designee	• Disclose to the accepting physician all information regarding the donor's medical, social, and sexual history as well as any known conditions that may be transmitted by the donor organ by documenting in the Donor Highlights section of DonorNet. • Ensure that ***O 3.033-1 Increased Risk Disclosure*** is completed by those off-site representatives from each accepting transplant center prior to transplant. • Upload the completed ***O 3.033-1 Increased Risk Disclosure*** to the EMR.

4) Materials and/or Equipment.

a) None.

5) Procedure.

a) Initiation of ***O 3.033-1 Increased Risk Disclosure***.

i) [redacted] utilizes a 2-person verification to ensure that donors are appropriately documented as increased risk.

Responsible Person	Step	Action
AOC/Designee	1	Instruct the CDC to initiate and check applicable risk factors on ***O 3.033-1 Increased Risk Disclosure*** as defined by PHS.

b) Completion of ***O 3.033-1 Increased Risk Disclosure***.

Responsible Person	Step	Action
CDC	1	Review and send the form to the CAT.
CAT/Designee	2	• Upload ***O 3.033-1 Increased Risk Disclosure*** to DonorNet and inform the transplant center representative that the form is available on DonorNet for their review prior to transplant. • Communicate the risk factor(s) or condition(s) with each accepting transplant center representative by documenting details in the donor highlights section of DonorNet.

CDC	3	If the accepting transplant center comes on site to recover the organ, ensure that the transplant center representative prints and signs their name in the spaces provided, prior to transplant. • Sign the form once the signatures of all onsite recovery teams have been obtained.
CAT/Designee	4	If the accepting center does not come on site to recover, or if recovery has already taken place, send the form to the transplant center representative to be reviewed and signed. • Sign the form once all signatures have been obtained by the accepting transplant surgeon or designee.
CDC CAT/Designee	5	• All signatures must be obtained prior to the date/time of organ transplant. • Contact the AOC/Designee if there are any problems obtaining signatures in a timely manner and document the circumstances in the EMR *Case Notes*. • A copy of the signed form is made available to each transplant center for their records. • The original signed form(s) is uploaded to the EMR. o In those cases where the CAT has obtained signatures from the centers that were not onsite to recover, there may be multiple original signed forms.

6) Attachments.

a) O 3.033-1 Increased Risk Disclosure.

7) Referenced and Related Procedures.

a) L 5.000 Conducting the Uniform Donor Risk Assessment Interview.
b) L 17.000 Blood Sample Suitability.

8) Standards and Regulations.

a) Association of Organ Procurement Organizations (AOPO) Standards; CL 8.1.
b) Center for Medicare and Medicaid Services (CMS) 42 CFR Chapter IV § 486.346 (a).
c) Organ Procurement and Transplantation Network (OPTN): 2.4; 2.5.
d) 2013 PHS Guideline for Reducing Human Immunodeficiency Virus (HIV), Hepatitis B (HBV), and Hepatitis C (HCV Through Organ Transplantation).

Property Of

INCREASED RISK DISCLOSURE

OPTN ID _____ Donor ID _____

This donor meets one or more of the PHS criteria outlined below as determined by the medical/social history, physical examination, and/or laboratory evaluation & has been identified as being at increased risk for recent HIV, HBV, or HCV infection. The risk factors that apply to this donor are checked below.

Source: The PHS Guideline for Reducing Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), & Hepatitis C Virus (HCV) through Organ Transplantation (2013).

PHS Increased Risk Factors for Recent HIV, HBV, or HCV Infection:

1	☐	People who have had sex with a person known or suspected to have HIV, HBV, or HCV infection in the preceding 12 months.
2	☐	Men who have had sex with men (MSM) in the preceding 12 months.
3	☐	Women who have had sex with a man with a history of MSM behavior in the preceding 12 months.
4	☐	People who have had sex in exchange for money or drugs in the preceding 12 months.
5	☐	People who have had sex with a person who had sex in exchange for money or drugs in the preceding 12 months.
6	☐	People who have had sex with a person who injected drugs by intravenous, intramuscular, or subcutaneous route for nonmedical reasons in the preceding 12 months.
7	☐	A child who is ≤ 18 months of age and born to a mother known to be infected with, or at increased risk for, HIV, HBV, or HCV infection.
8	☐	A child who has been breastfed within the preceding 12 months and the mother is known to be infected with, or at increased risk for, HIV infection.
9	☐	People who have injected drugs by intravenous, intramuscular, or subcutaneous route for non-medical reasons in the preceding 12 months.
10	☐	People who have been in lockup, jail, prison, or a juvenile correctional facility for more than 72 consecutive hours in the preceding 12 months.
11	☐	People who have been newly diagnosed with, or have been treated for, syphilis, gonorrhea, Chlamydia, or genital ulcers in the preceding 12 months.

PHS Increased Risk Factors for Recent HCV Infection Only:

12	☐	People who have been on hemodialysis in the preceding 12 months.

PHS Increased Risk Factors for Disease Transmission:

13	☐	A medical/behavioral history could not be obtained or risk factors could not be determined.
14	☐	A hemodiluted specimen was used for serological testing and the donor's risk for infection is unknown. The following tests were completed using hemodiluted specimens:

This form has been reviewed with AOC _____ Date _____ Time _____

by the CDC: _____

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

This form has been reviewed by the representative of the accepting transplant center or designee:

TX Center	Contact Name (print)	Signature	Title	Date	Time

The CDC will sign the form that contains signatures from all centers on-site to recover. The CAT/Designee will sign the form that contains signatures from all other centers.

[redacted] Staff Signature _____ Date _____ Time _____

O 3.033-1 Increased Risk Disclosure, Rev 15
IMP. 05/014/16

Appendix E

[redacted]

[redacted] Playbook

Hard Stop Process

Protecting Patient Safety

The purpose of this document is to develop a process to ensure review of all available donor patient medical information – potentially affecting patient safety. This review should be prior to determining final suitability for donation (BD and DCD donors) and following brain death declaration.

This outstanding medical information may include, but not be limited to, previous medical records, pathology reports, consultations and/or additional information from family members.

The process will include placing a "Hard Stop" on the donation process until the relevant medical information is obtained and reviewed. The specifics are as follows:

1. **The Hard Stop will be at the discretion of the [redacted] Administrator On-Call (AOC) and/or Medical Director.**

2. **The Hard Stop process will include, but not be limited to: ABO incompatibility/Indeterminate results, massive transfusion protocols, questionable brain death declaration and unresolved suspicion of cancers and/or infectious disease processes.**

3. **The Hard Stop process will prohibit setting an OR time until a resolution is reached or final suitability for donation is determined.**

4. **The initiation and release of a Hard Stop must be communicated to the Clinical Donation Coordinator (CDC) and the AOC and documented in the [redacted] electronic record under the "Case Notes."**

5. **The Hard Stop may only be "released" by the AOC and/or [redacted] Medical Director.**

6. **Once a Hard Stop is released, the OR scheduling may proceed.**

The Hard Stop process may be initiated for any event where there is outstanding patient information available and that information may affect patient safety during transplant.

However, this practice will be particularly helpful when there is an ABO determination issue, cancer/infectious disease suspicion, and when other patient charts need to be reviewed to confirm the presence or absence of a previous cancer/infection.

Any [redacted] staff may contact the AOC or Medical Director to request or recommend a Hard Stop.

Please contact the [redacted] AOC or Medical Director with any questions regarding this issue or any concerns regarding patient safety.

[redacted]

From: [redacted]
Sent: Wednesday, December 26, 2018 1:45 PM
To: [redacted]
Cc:

Subject: Secure: RE: [redacted] Response

[redacted]:

I have read through your response.

First, Do you know when the full, completed RCA will be available? This case will be proceeding to the MPSC for the February meeting, and my deadlines to have cases ready for review is 1/17/19. I can extend the date to receive the RCA to no later than **noon** on **Friday, 1/18/19**. Will the RCA be done by then?

Second, can you please clarify an issue for me? According to the response:

Sample #1 was drawn on 11/24/18 at 23:09 and resulted in O.
Sample #2 for VRL was drawn on 11/25/18 at 19:00 and was indeterminate.
Sample #3, to confirm ABO from Sample #1, was drawn on 11/25/18 at 19:50 and resulted in O.

However, the [redacted] verification form included notes that "due to indeterminate results from VRL a second Hosp ABO was ordered." I do not see when a fourth ABO was ordered or drawn *after* the VRL results of indeterminate came back. The case summary states that after the VRL indeterminate result came in, organs were allocated as O given that two hospital ABOs were drawn at different intervals and both found O. I do not see a fourth draw for the purposes of determining ABO – I only see draws that were for tissue or to be sent with the organs.

Can you please clarify?

[redacted]
Safety Analyst

UNOS UNITED NETWORK FOR ORGAN SHARING

Matching organs. Saving lives.

[redacted]

[redacted]

www.unos.org

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CISCO

Secured Message

Reply ReplyAll Forward

From: [redacted]
To: [redacted]@unos.org>
CC: [redacted]
Date: 12/28/2018 09:17:22 AM [redacted]
Subject: RE: Secure: RE: [redacted] Response

Good Morning [redacted]
Below is [redacted] response to your questions in your email.

Question #1
The Joint RCA between [redacted] and [redacted] is scheduled for January 10th, 2019. I can try to have [redacted] preliminary RCA findings completed by 1/18/2019 but will need to confirm with [redacted] that any findings and corrective actions involving their organization will be available by 1/18/19. I will reach out to their quality department on Wednesday 1/2/19 for their timeline.

Question #2
Sample #1 was on 11/24/18 at 23;09
Sample #2- the VRL sample was drawn for serology testing and not specifically for ABO typing- ABO typing is part of the testing panel. The results were indeterminate. [redacted] had initially planned to order another ABO unless we could locate a hospital ABO with a different date and time that verified the primary ABO result. [redacted] found a second hospital ABO - with a different date and time - so we did not re-run the ABO typing.
Sample#3 was on 11/25/19:50 - this sample was used as the 2nd ABO
Sample #4- there was not any additional samples drawn since sample #3 was available, drawn at a different date and time and the results were the same as sample# 1.

If you have any additional questions please email me.
[redacted]

----------Original Message:

From: [redacted]e@unos.org>
To: [redacted]
CC: [redacted]
Date: 12/26/2018 01:44:44 PM [redacted]
Subject: Secure: RE: [redacted] Response

[redacted]

I have read through your response.

First, Do you know when the full, completed RCA will be available? This case will be proceeding to the MPSC for the February meeting, and my deadlines to have cases ready for review is 1/17/19. I can extend the date to receive the RCA to no later than noon on Friday, 1/18/19. Will the RCA be done by then?

[redacted]

From: [redacted]
Sent: Wednesday, January 16, 2019 6:29 PM
To: [redacted]
Cc: [redacted]
Subject: [redacted] and [redacted] Hospital Root Cause Analysis AFKY198
Attachments: RCA UNOS ABO Incompatibility [redacted] and [redacted] 01.16.19.pdf; [redacted] 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 [redacted] and [redacted] Hospital regarding Donor [redacted] This write up includes the working corrective action plan from [redacted] Attached is also a letter from [redacted] 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], [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

[redacted]

[redacted]

[redacted]

[redacted]
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/ [redacted] 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: [redacted]
LUNGS: [redacted]
LIVER: [redacted]
PANCREAS: [redacted]
INTESTINE: No list run, 209 (Multiple pressors)
KIDNEYS: 1 & 2 to [redacted]
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 [redacted] Communication Center received a call from transplant coordinator at [redacted] in reference to the donor blood typing. The call was referred to the Organ AOC. The AOC spoke with the coordinator a t[redacted] who indicated they has tested the blood they received with the pancreas and the ABO came back "A". [redacted] 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. [redacted] 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- [redacted] 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, [redacted] 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 [redacted] 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 [redacted] 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: [redacted] Hospital could not share their policies due to the proprietary nature of [redacted] 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 [redacted] 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 [redacted] 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?	[redacted] 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?	[redacted] there are several policies related to specimen drawn for donor evaluation, ABO Verification and organ allocation. [redacted] Hospital has policies related to ABO testing, indeterminate results test and reporting ABO results: NOTE: Due to the proprietary nature of [redacted] policies, they are not permitted to send the policies outside of our organization.
	Did the staff involved follow the policy /SOP as outlined?	[redacted] Yes [redacted] Hospital- Yes
	Were the staff involved aware of the policies/SOP?	[redacted] Yes [redacted] 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. [redacted] 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 [redacted] 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.**

[redacted] **Blood Bank**		
	Were there any deviations in the testing of the ABO in this donor (patient)?	**None based on [redacted] 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.**

[redacted] **Indeterminate Results**		
	What is the process and communication for indeterminate typing results? Is this in policy or a practice?	**[redacted] 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?	**[redacted] 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?	[redacted] Yes – the CEO was notified immediately. [redacted] Hospital-[redacted] 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 [redacted] and [redacted] 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.

Action Plan and Monitoring

Containment Plan

Indeterminate ABO typing- if blood typing results - for any test - indicates that the sample results are indeterminate:

- [redacted] 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, [redacted] 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

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

[redacted]

Date: January 16, 2019

To: [redacted]

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

[redacted]

[redacted]

Staff Summary

Please note that this accompanying summary information is included to only supplement the original documentation, and assist the Committee members in their thorough review of the source documentation provided in the site survey, desk review or case investigation packet.

Please review the summary of potential policy violations and corrective action plans in the attached packet to determine if a policy violation exists, to determine if the corrective action plan addresses the problem, and to identify an appropriate recommended action. Please provide a basis for your decision in the comments section.

Case Description: Lab 614270 reported that OPO 660760 shipped a kidney to an accepting center. The accompanying tissue typing material label did not include the donor ID, a second unique identifier, or date and time of draw.

Possible Action (based on historical MPSC action in similar cases):

- Notice of Noncompliance for Policy 16.3.C

MPSC History:

- November 2019: Notice of Noncompliance for an allocation error
- July 2019: Release from monitoring
- March 2019: Notice of Noncompliance and monitoring for an ABO determination and reporting error that led to incompatible transplants
- January 2018: Notice of Uncontested Violation for shipping a kidney without required information on the external label and required paperwork

Survey Information: A routine on site survey of the OPO occurred on February 6, 2018. The OPO had a clinical score of 96 percent and some administrative errors. The MPSC reviewed the results of the survey at its meeting in October 2018 and recommended that UNOS conduct a follow-up desk review of the OPO in one year.

UNOS conducted the follow up desk review on September 26, 2019. At its meeting in February 2020, the MPSC reviewed the results of this survey and recommended that UNOS conduct a follow-up desk review of the OPO's compliance with Policy 2.6.B in nine months.

OPO Volumes:

Year	Donors Recovered	Organs Recovered
2017	166	626
2018	181	632
2019	183	702
2020	65*	211*

*As of June 3, 2020

Historical MPSC Actions: The MPSC would typically issue a Notice of Noncompliance in cases involving tissue typing labeling errors. The MPSC has considered higher actions (Letter of Warning, etc.) if the

member has a significant compliance history, if the nature of the violation poses a significant patient safety risk, if the member did not adequately correct the root cause of the violation, etc.

Voting Instructions:

- Vote YES if you agree with the proposed decision above.
- Vote NO if you feel that a different action is warranted; you have concerns about patient safety, the member's history, or CAP; or you would like for the case to be placed on the discussion agenda. Please leave a detailed comment include your recommendation and any concerns.

Issue Involves: OPO 66076O
Issue Reported by: Lab 61427O

Issue: Lab 61427O reported this event through the OPTN Improving Patient Safety Portal. OPO 66076O shipped a right kidney to the accepting transplant center. The accompanying tissue typing material label did not include the donor ID, a second unique identifier, or date and time of draw.

Relevant OPTN Policy:
16.3.C Internal Labeling of Blood and Tissue Typing Materials: "Each separate specimen container of blood tissue typing material must have a label...The label must include the donor ID and at least one of the following identifiers: Locally assigned unique ID, Donor date of birth, Donor initials...Additionally each specimen should be labeled with both of the following: 1. The date and time the sample was procured..."

Relevant Correspondence:
Inquiry to OPO 66076O - sent on February 25, 2020
Response from OPO 66076O - received on March 9, 2020
Notification letter to OPO 66076O - sent on March 17, 2020

Member Response:

OPO 66076O reported:

- OPO 66076O used TransNet to label the specimen containers of tissue typing material for the right kidney.
- During kidney perfusion, a plastic biohazard bag containing the tissue typing material was stored in the pump. When OPO 66076O staff lifted the lid to the pump, the plastic biohazard bag stuck to the lid and fell to the floor breaking two yellow top tubes. The containers of blood and lymph nodes were unbroken but contaminated.
- OPO 66076O staff used water and a towel to remove blood on the specimen containers. OPO 66076O indicated that although specimen containers were previously properly labeled, the required information was erased during the cleansing process, and that staff did not identify the erasure or consider relabeling.
- OPO 66076O attributes the erasure of required information to "defective ink of TransNet label".
- The accepting transplant center notified OPO 66076O of the labeling issue and provided pictures of the specimen containers with blank labels.

OPO 66076O corrective actions:

- OPO 66076O reinforced with staff the importance of being careful when opening the lid of the kidney pump to prevent dislodging any stored materials.
- OPO 66076O instructed staff to review labels to ensure that information is intact and noted that TransNet supplies provided by UNOS, specifically the ink, is subject to easy erasure.

UNOS Safety Analyst Note:

- UNOS supplied printers do not use ink. Information is written using thermal energy to prevent smearing and erasure, onto labels able to withstand cold and wet conditions within organ packaging.
- This event was reviewed with a UNOS staff member with TransNet expertise. He communicated that there have not been reports of a similar issue.

SFC OPTN Hearing
Exhibit B.7

Confidential Information

Printed 2/11/2020 12:43:09 PM

Improving Patient Safety

Safety Situation Details

Situation ID [redacted] **Reported 02/11/2020**

The goal of the Improving Patient Safety system is to collect information about safety related incidents occurring system-wide, in order to increase organ utilization and decrease the morbidity and mortality of transplant patients.

What is a Safety Situation?
A situation or activity that affected or could have affected patient safety.

What to report:

- Any patient safety situation
- Any other situation that causes a safety concern from a transplantation, donation, and/or quality perspective.

Please report such situations in a timely manner.

Situation Information

Reporting Institution: * [redacted] **Hospital Based Lab (Member)**

Type of Safety Event (Choose all categories and subcategories that are applicable): *

- ☐ Communication
- ☐ Data Entry
- ☐ Transportation
- ☐ Packaging/Shipping
- ☑ Labeling
  - ☐ ABO
  - ☐ Donor ID
  - ☐ Required information missing
  - ☐ Transcription error
  - ☐ Switched laterality for Labeling
  - ☐ Incorrect test results
  - ☑ Blood/nodes/spleen labeling issue
  - ☑ Missing label
  - ☐ Other (please describe in the description field below)
- ☐ Recovery Procedure/Process
- ☐ Transplant Procedure/Process
- ☐ Testing
- ☐ Organ Allocation/Placement
- ☐ Other (please describe in description field below)

The Issue reported involves the following (choose all categories that are applicable): *

- ☐ **Recipient/Candidate**
- ☐ **Donor Organ/Extra Vessels**
- ☑ **Other (please describe in the description field below)**

SFC OPTN Hearing
Exhibit B.7

Date Event Occurred: * 02/07/2020

Detailed Description of the Event: * Received donor LN container and red top tube from transplant hospital. The LN container was labeled with only "3 Nodes". There was no donor information on either the LN container or red top tube. Donor ID: [redacted]

Has a root cause analysis (RCA) been completed? * ○ Yes ◉ No ○ In Progress

Please specify additional details regarding the RCA:

Please upload any relevant attachments:

File Name	Date Uploaded	Delete
[redacted] tube side 2.pdf	02/11/2020	
[redacted] tube side 1.pdf	02/11/2020	
[redacted] biohazard bag label.pdf	02/11/2020	

Contact Information

Who at your institution should UNOS contact about this case?

First Name: * [redacted] **Last Name:** * [redacted]

Phone contact (Enter at least one): *

Office: [redacted] **ext.** **Pager/beeper:** **ext.**

Mobile: **ext.** **Other:** **ext.**

Email: * [redacted]

Other contact info:

UNOS Only

Reported by: [redacted]

Initial UNOS Action

Date: * 02/11/2020 **Staff member:** [redacted]

Status: * In process **Urgency:** * Low

Category: * Critical

Potential policy violation: ○ YES ○ NO

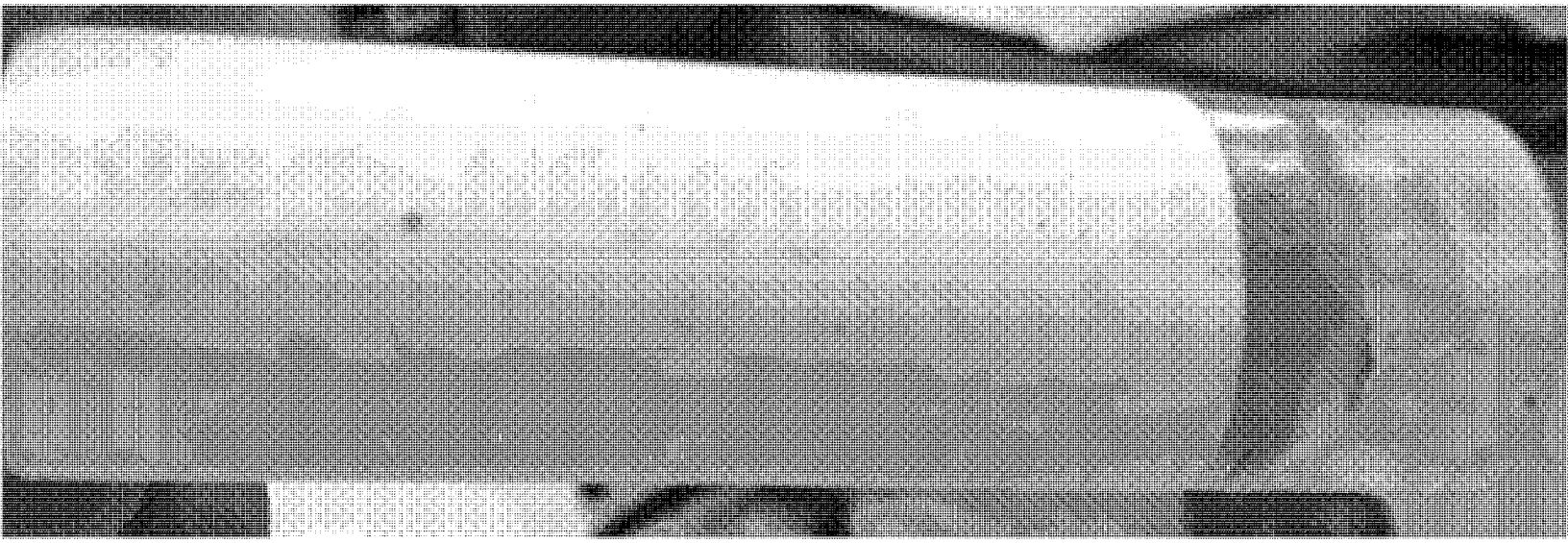
Committee notification? ○ YES ○ NO

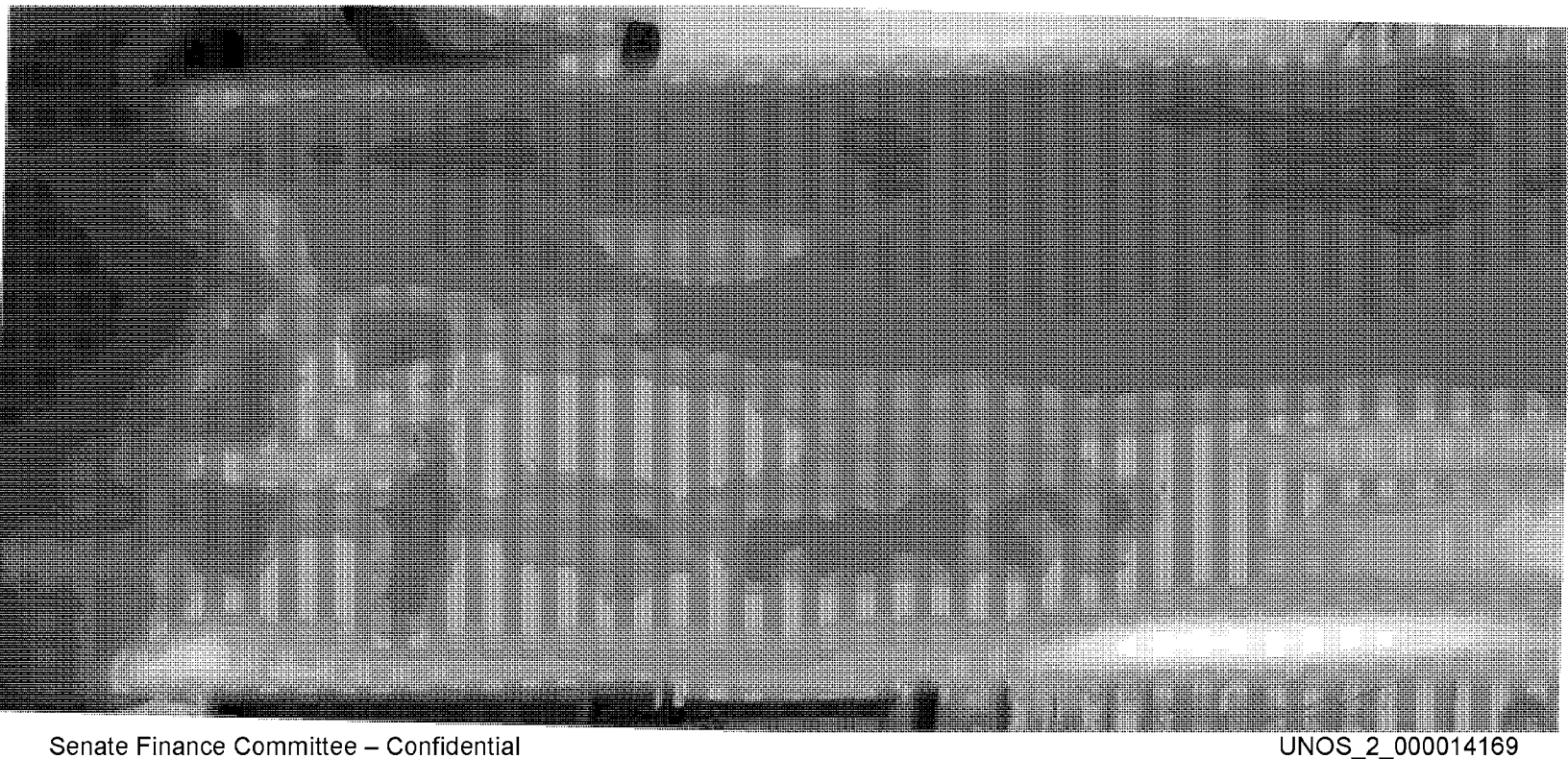
Type of Safety Event (Choose all categories and subcategories that are applicable):

- ☐ Communication
- ☐ Data Entry
- ☐ Transportation
- ☐ Packaging/Shipping
- ☐ Labeling
- ☐ Recovery Procedure/Process
- ☐ Transplant Procedure/Process
- ☐ Testing
- ☐ Organ Allocation/Placement
- ☐ Other (please describe in description field below)

Attachments


Donor ID: [redacted] ABO: A
DOB: [redacted] Donor Initials: [redacted]
Local ID:
Collected: 02/01/2020 19:07 EST By: [redacted]
NOTES
[redacted]
BLOOD
10H:AZARD
CardinalHealth





OPTN ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

[redacted]

CONFIDENTIAL MEDICAL PEER REVIEW

February 25, 2020

VIA SECURE EMAIL

[redacted]

Dear [redacted]:

The United Network for Organ Sharing (UNOS) serves as the Organ Procurement and Transplantation Network (OPTN) under contract with the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services. Under that contract, UNOS staff review reported or identified patient safety and/or public health-related concerns associated with organ donation and transplantation occurring within the OPTN.

UNOS' Member Quality staff screen all reports to determine whether the matter suggests a risk or threat to patient safety or public health. Often additional information is needed from the involved OPTN member(s) to finalize the assessment of threat. If the matter is assessed as both time-sensitive and serious, this department will alert UNOS and/or OPTN Membership and Professional Standards Committee (MPSC) leadership and, under that direction, work with OPTN member(s) to alleviate the threat.

UNOS' Member Quality Department staff also screen all reports to determine if there is a possible violation of OPTN bylaws or policies associated with the matter. Again, additional information is typically needed from OPTN member(s) involved in order to complete the assessment.

We are currently reviewing a labeling error by [redacted] ([redacted]) for donor [redacted]. Our preliminary analysis indicates that tissue typing material accompanying the right kidney, specifically the separate specimen containers of lymph nodes and blood, did not have labels indicating the donor ID, any other identifiers or the date and time the specimen was procured.

We are contacting you to obtain a complete understanding of what occurred. We appreciate as much detail as you can provide. Any information you provide that suggests a potential policy or bylaw violation, or which may pose a threat to transplant or donor patient health or public safety may be referred for review by UNOS leadership, including the MPSC, and in some cases the OPTN Board of Directors.

CONFIDENTIAL MEDICAL PEER REVIEW

Please address the following issues related to the labeling error:

- Provide a detailed summary of the event and specify if staff deviated from [redacted] protocol. Include why [redacted] staff did not use TransNet to label the separate specimen containers and explain why the error was not identified during the labeling verification process.
- Provide a root cause analysis for this event, if available.
- Describe actions taken by [redacted] to resolve the issue with the receiving right kidney transplant center and/or tissue typing lab once the error was identified.
- Describe any other labeling errors reported to [redacted] by receiving transplant centers for this donor. Note whether the error resulted in any delay of transplant, if applicable.
- What corrective actions, if any, have been implemented or are planned as a result of this event? If corrective actions include revisions to existing documents, please provide those documents with the changes easily identifiable (i.e., highlight changes, etc.).

The OPTN bylaws and policies guide the sequence of allocation and wait listing practices of OPTN members in an effort to assure equitable organ allocation for transplant. The bylaws and policies also guide safe and effective practice connected to organ transplantation and living donor care. UNOS is responsible for monitoring compliance by OPTN members with these OPTN obligations, as well as for processing reports of transplant-related patient safety and living donor safety.

The OPTN MPSC, and in certain cases, the OPTN Board of Directors, perform the peer review functions of the OPTN. Please be aware that this correspondence and all documents and information requested by UNOS staff, on behalf of the OPTN, are protected by applicable peer review statutes and will not be disclosed. For this reason, all associated reports, inquiries, deliberations, findings, recommendations, and actions must be kept confidential. This means we will not be able to provide you with the results of our investigation.

I look forward to hearing from you by **March 10, 2020**. Responses can be sent via mail, email and/or fax. I can be contacted at [redacted] Thank you in advance for providing the additional information requested.

Sincerely,

[redacted]
Safety Analyst
UNOS Member Quality

cc: [redacted] OPTN Alternate Representative
[redacted] Director, UNOS Member Quality

[redacted]

From: [redacted]
Sent: Monday, March 9, 2020 3:17 PM
To: [redacted]
Subject: [EXTERNAL] [redacted] Response 200225 Unlabeled Lymph Node and Blood tube Donor [redacted]
Attachments: [redacted] Response 200225 Unlabeled LN and Blood tube 03.09.2020.pdf

[redacted]

Attached you will find [redacted] response to the unlabeled lymph node container and blood tube for donor [redacted]. The response includes the answers to the questions you posed in your letter dated 02/25/2020 with supporting documentation including the causal review.
If you have any questions or need additional information you can either email me at [redacted] or call me directly at [redacted].

[redacted]

[redacted]

[redacted]

This e-mail message, including any attachments, is for the sole use of the intended recipient(s) and may contain confidential and privileged information. Any unauthorized review, use, disclosure or distribution is prohibited. If you are not the intended recipient, please contact the sender by reply e-mail and destroy all copies of the original message.

[redacted]

March 9, 2020

[redacted]
Sate Analyst
UNOS Member Quality
Organ Procurement and Transplantation Network (OPTN)
[redacted]

Dear [redacted],

We are in receipt of your letter dates February 25, 2020 regarding the labeling error for donor [redacted] Below is our response to the questions you poses in the letter:

- Provide a detailed summary of the event and specify if staff deviated from [redacted] protocol. Include why [redacted] staff did not use TransNet to label the separate specimen containers and explain why the error was not identified during the labeling verification process.

  [redacted] **Response:**

  There were no deviations from [redacted] Protocol – [redacted] Policy O4.140 Labeling, Verification, Packaging and Transport section E Labeling and Packaging Organ for Transport (see attached policy Appendix A) states

  i) All organs, vessels, and specimens must be packaged in a sterile environment.
  ii) **All organ labels are created using TransNet.**
  iii) All organ and specimen labels are verified by two qualified health care professionals using source documents before leaving the OR.
  iv) **TransNet is used as described by UNOS to automate the labeling process.**

  Transnet labels were used to label the blood tube and the container containing the tissue typing material (lymph nodes). (See attached Transnet audit log Appendix B). The case review and interview with the involved staff indicated that the tissue typing material and blood tubes were in a plastic biohazard bag stored in the kidney pump while the kidney was being perfused. When the Clinical Donation Specialist (CDS) lifted the lid the biohazard bag was stuck to the lid and fell to the floor which cause the two yellow top tubes to break. The red top and spleen/nodes container were unbroken and covered in blood. The CDS used water and a towel to clean the tubes before repackaging and shipping the kidney. The tubes were labeled but it appears that the when the labels were cleansed after the spill the information was washed off. (See pictures of the biohazard bag and tube Appendix C)

[redacted]

[redacted]

- Provide a root cause analysis for this event, if available.
  See attached causal analysis

- Describe actions taken by [redacted] to resolve the issue with the receiving right kidney transplant center and/or tissue typing lab once the error was identified.
  [redacted] was notified by the transplant center of the labeling issue and received pictures of the tubes that were labeled but the information is washed off.

- Describe any other labeling errors reported to [redacted] by receiving transplant centers for this donor. Note whether the error resulted in any delay of transplant, if applicable.
  There were no other reported labeling issue reported to [redacted] by any of the receiving transplant centers.

- What corrective actions, if any, have been implemented or are planned as a result of this event? If corrective actions include revisions to existing documents, please provide those documents with the changes easily identifiable (i.e., highlight changes, etc.).
  The Transnet labels and printers are supplied to the OPO by UNOS and it appears that the ink was able to be washed off with water and a towel. We have encouraged staff to be mindful when opening container or lid to ensure that whatever is stored is not dislodge and has the potential to fall and break.

If you have any questions or need additional information, please contact me either by email at [redacted] or you can call me directly at [redacted]

Sincerely,

[redacted]

[redacted]

[redacted]

Causal Review
Donor-[redacted]
DOB [redacted]
DOD [redacted]
Cross Clamp 02/07/2020

Donor History:
17 year old male with reported fever, chills, URI and flulike symptoms on 01/24/2020. Was seen by PCP on 01/25/2020 but tested negative for flu and strep throat. It was determined symptoms were viral. Was seen again with no improvement in symptoms and started on antibiotics. His fevers continued and 02/02/2020 reported to experience left leg weakness and facial drooping on the left side. His symptoms progressed to the inability to use his left side extremities and falling hitting his head. He was taken to the ER and head CT scan indicated a 6mm midline shift and right side extra axial fluid collection which was felt to be blood or empyema. He was taken to the OR for craniectomy. When the dura was opened pus came out under fairly significant pressure. He was left intubated, transferred to PedsICU and started on broad spectrum antibiotics. On 02/03/2020 a third CT scan was performed indicating an 8mm midline shift with a significant amount of edema but no significant extra axial fluid collection. He was transferred to another hospital for a higher level of care but progressed to brain death and was pronounced on 02/05/2020 at 10:00 via clinical exam and apnea testing. Authorization was obtained from the mother on 02/05/2020 at 12:45.

Organ allocation final disposition:
Heart-[redacted]
Lungs- ruled out in the OR
Liver-[redacted]
Left Kidney-[redacted](for Kidney/Pancreas)
Right Kidney-[redacted]
Pancreas-[redacted](for Kidney/Pancreas)
Intestine- not recovered

Recovery/Event timeline:
02/07/2020

16:27	Donor taken to OR
16:57	incision
18:47	Heparin given
18:58	cross clamp/initial flush
19:02	nodes recovered
19:35	liver recovered

[redacted]

[redacted]

19:40 right and left kidneys recovered
20:32 right kidney placed on pump

02/08/2020
06:40 right kidney taken off pump to ship to [redacted]

Incident interview with Clinical Donation Specialists regarding labeling of lymph nodes and blood tubes.
Per CDC [redacted], the tissue typing materials were stored in the kidney pump while the kidney was being perfused. When the CDS lifted the lid, the tissue typing was stuck to the lid and fell on the floor. This caused the two yellow top blood tubes to break.
The red top and spleen/nodes containers were unbroken, but covered in blood. CDSs [redacted] used water and a towel to clean the tubes before repackaging and shipping the kidney. Given that the tube and container were labeled with a Transnet label prior to being placed on the pump they did not relabel or see that the information on the label had been wiped off during cleaning off the blood.

Root Cause:
Defective ink of Transnet label allowing for the information to be wiped off if label becomes saturated.

Corrective Action:
The Transnet labels and printers are supplied to the OPO by UNOS and it appears that the ink was able to be washed off with water and a towel. We have encouraged staff to be mindful when opening container or lid to ensure that whatever is stored is not dislodge and has the potential to fall and break. Staff have also been told to review the labels to ensure that the information is intact.

[redacted]

Appendix A

[redacted]	Standard Operating Procedure **Organ Recovery Services Manual**	Document Number	04.140
		Revision Number	16
	Labeling, Verification, Packaging, and Transport	Revision Date	09/26/19
		Page 1 of 5	

1) Policy.

a) It is the policy of [redacted] to:
   i) Uniformly label and package all specimens and organs.
   ii) Verify the accuracy of labels and document the verification.
   iii) Verify the accuracy of each packaged organ and its contents.

b) The purpose of this document is to describe the procedure for completing labels, packaging items for transport, verifying labels & organ packages, and transporting organs.

2) Definitions and/or Acronyms.

Term	Definition
ABO	Type A, B, O, or AB blood and subtype, if applicable.
CAT	Clinical Allocation Technician.
CDC	Clinical Donation Coordinator.
CDS	Clinical Donation Specialist.
Disposable shipping box	A corrugated, cardboard outer container coated with a water resistant substance with at least 200 pound burst strength. The insulated inner container is at least 1.5 inches thick, or its R-factor equivalent.
EMR	Electronic Medical Record.
IAW	In Accordance With.
OPTN	Organ Procurement and Transplantation Network.
OPTN ID	A unique identification assigned when an organ donor is registered in DonorNet. • Also known as UNOS ID, UNOS # or OPTN#.
OPTN label	Standardized label distributed by OPTN and described as follows: • Exterior OPTN label: A color-coded, organ specific 8"x11" label. • Interior OPTN label: A color-coded, organ specific 5"x7" label. • Exterior Perfusion label: A 4"x8" label for the kidney perfusion machine.
OR	Operating Room.
Organ transport container	The disposable box, cooler, or perfusion machine in which the organ will be transported.
Source Documents	An original record of results, or a photocopy or digital copy of the original record. Examples of source documents include laboratory printouts, DonorNet, Match Run printouts from DonorNet, EMR documentation, and hospital medical record.
Specimen	Blood tubes, tissue typing materials, biopsy, or biopsy slide.
TransNet™	An organ tracking system developed and distributed by the OPTN Contractor that uses barcode technology to generate printed labels for specimens, chart, and organ packaging and tracking. TransNet is the preferred labeling system for [redacted]
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 CDC, CDS, and CAT.

Position	Responsibility
CDC CDSCDC	Label and package specimens using TransNet.
CDS	Label internal organ containers, specimen containers, and organ transport containers.
CAT CDC CDSC	Facilitate the transport of the donated organ to the local transplant program, or the export of the organ IAW the arrangements made by the accepting center.

4) Materials and/or Equipment.

a) Specimen(s) to be sent for testing.
b) Applicable transport container for each specimen or organ.
c) Packing tape.
d) OPTN labels.
e) Wet ice.
f) Biohazard bag.
g) Zip ties.
h) TransNet labeling system.
i) PPE IAW ***S 1.000-4 PPE Requirements - Organ***.

5) Procedure.

a) Labeling Specimens.
i) TransNet is used as described by UNOS to automate the labeling and verification process.
ii) A 2-person verification of specimen labels is performed using TransNet before the specimens are transported.
iii) Labels may be corrected IAW ***Q 9.000 Labeling of Organs and Tissue Products***.

Responsible Person	Step	Action
CDC CDS	1	All specimens drawn for donor evaluation purposes will be labeled with a TransNet label. • See ***O 4.140-11 TransNet user Guide for further TransNet instructions***.
CDC CDS	2	Coroner blood will be labeled with a hospital label IAW ***L 21.000 Coroner/Autopsy Cases***.

b) Packaging & Transport of Specimens.

Responsible Person	Step	Action
CDC	1	Package all specimens in the appropriate transport box for shipment. • Complete ***O 1.100-1 HLA Deceased Donor Requisition*** for each draw time of specimens being sent to HLA and place inside the transport box. • Complete all labels affixed to the box, as applicable.
CDC	2	HLA specimens will be transported to the HLA lab and cross-match blood will be shipped to the applicable transplant center.
CDC CDS	3	Local couriers may be used to transport specimens. • Complete any necessary paperwork (e.g. Bill of Lading, courier billing form) and document the Donor ID and the specimen type on the applicable form. • Document transportation details in the EMR on the *Organ Pre-OR/Donor Acquisition Medical Medical Provider Information* page. If a local courier is unavailable, [redacted] will be used for courier services. Call the Customer Center to arrange transportation with [redacted]. • See ***O 4.140-8 [redacted] Resources*** for further details about [redacted] courier services.

c) Preparing the Disposable Shipping Box for Recovered Organs.
i) One disposable shipping box per organ (or organs enbloc) will be used. Disposable shipping boxes are single-use only and re-use is prohibited.

Responsible Person	Step	Action
CDC CDS	1	Place the biohazard bag inside of the disposable shipping box.
CDC CDS	2	Place the insulated container inside of the biohazard bag.
CDC CDS	3	Place a regular plastic bag inside the insulated container.
CDC CDS	4	Put a thin layer of wet ice across the bottom of the regular plastic bag.
CDC CDS	5	Complete the applicable exterior OPTN label using TransNet and securely affix the label to the outside of the disposable shipping box.

		• The exterior OPTN labels may be layered on the outside of the disposable shipping box, as needed, with the identifying information remaining visible.

d) Preparing the Cooler for Recovered Organs.
   i) There may be times when an organ is packed in a cooler instead of a disposable shipping box.
   ii) Coolers may NOT be used when organs are being shipped on a commercial airline. In those cases organs must be packaged in a disposable shipping box.

Responsible Person	Step	Action
CDC CDS	1	Line the cooler with a biohazard bag.
CDC CDS	2	Put a layer of wet ice in the bottom of the biohazard bag.
CDC CDS	3	Complete the applicable exterior OPTN label using TransNet and securely affix the label to the outside of the cooler. • The exterior OPTN labels may be layered on the outside of the disposable shipping box, as needed, with the identifying information remaining visible.
CDC CDS	4	Coolers may be re-used when the cooler has been properly cleaned and sanitized and all previous labels have been removed. • Cleaning is documented on ***O 7.030-6 Organ Lab Maintenance Log.***

e) Labeling and Packaging Organs for Transport.
   i) All organs, vessels, and specimens must be packaged in a sterile environment.
   ii) All organ labels are created using TransNet.
   iii) All organ and specimen labels are verified by two qualified health care professionals using source documents before leaving the OR.
   iv) TransNet is used as described by UNOS to automate the labeling process.

Responsible Person	Step	Action
CDC CDS	1	Complete the applicable interior OPTN label using TransNet.
CDC CDS	2	After the organ is handed off of the back table, securely affix the interior OPTN label to the outermost layer of the organ packaging.
CDC CDS	3	The labeled organ is placed directly into the labeled insulated container.
CDC CDS	4	Cover the organ with ice. • This is considered "ice time" and will be documented on the organ label using TransNet. •If TransNet is unavailable, verification will be documented on the ***O 4.140-7 Organ Packaging and Labeling Verification***.
CDC CDS	5	Securely close the inside plastic bag around the ice in a manner to prevent leaking.
CDC CDS	6	As applicable, place the labeled biopsy specimen, nodes, spleen, yellow top tubes (tissue type samples) and red top tubes (ABO confirmation sample and/or toxoplasma sample) on top of the closed plastic bag inside the shipping container.
CDC CDS	7	Close the insulated container.
CDC CDS	8	Close the biohazard plastic bag securely around the insulated container in a manner to prevent leaking. • Note: This step is not necessary when using a cooler for transport.
CDC CDS	9	Place a copy of the ABO and the serology source documents into a plastic bag and place outside of the biohazard plastic bag inside of the shipping container. • All organs, including organs that are recovered and transplanted in the same hospital will include this documentation.
CDC	10	Close the shipping container and secure the flaps with packing tape.

CDS		

f) Organ Packaging Verification.
i) A 2-person verification of the labels and packaging is performed using TransNet before the organ is transported.
ii) TransNet is used as described by UNOS to automate the labeling and verification process.
iii) Labels may be corrected IAW ***Q 9.000 Labeling of Organs and Tissue Products***.

Responsible Person	Step	Action
CDC CDS	1	Ensure the following items are in each organ transport container. • The correct organ. • Biopsy specimen or slides (if applicable). • Tissue typing materials (if applicable). • Vessels (if applicable). • ABO and the serology source documents.
CDC CDS	2	Verification is performed and documented in TransNet. •If TransNet is unavailable verification will be documented on the ***O 4.140-7 Organ Packaging and Labeling Verification***. • See ***O 4.140-11 TransNet User Guide*** for further TransNet instructions.

g) Transportation.

Responsible Person	Step	Action
CDC/ Designee	1	Make the travel arrangements for local recoveries. This includes both arrival and departure arrangements for the local recovery team(s). • Arrange the ground transportation for any outside teams coming to recover. • Flight arrangements for outside recovery teams will be arranged by the recovering team.
CDS	2	The recovered organ may be transported in the custody of the recovering surgeon/designee back to the transplant center. • The kidneys and pancreas may remain in the custody of the CDS until handed over to a courier for transport to the accepting center, delivered directly to the local transplant OR, or returned to the [redacted] office for perfusion or discard. • The first and last name of all personnel who assume custody of the organ(s) and the date and time will be recorded in the EMR *Case Notes*.
CAT CDS	3	Make transportation arrangements for all organs post-recovery in conjunction with the accepting center. [redacted] may be used for transportation of exported organs. • Call the [redacted] Customer Center to make transportation arrangements. • A Sense Aware device must be securely attached to all exported kidney boxes via commercial airline. o Provide the unit number on the Sense Aware device to the Customer Center and attach the device to the box. o Confirmation emails will be sent to the CDS/CAT at predetermined transportation intervals. • Complete any necessary paperwork (e.g. Bill of Lading, courier billing form) and document the UNOS ID and the type of specimen on the applicable form. • See ***O 4.140-8 [redacted] Resources*** for further details about [redacted] courier services. • Any deviations to the shipping process outlined above (e.g. not using Sense Aware) will be pre-approved by the AOC/Designee and documented in the EMR *Case Notes*.

CDS	4	In cases where the organ recovery and the transplant take place at the same hospital and the organ can be transported via a sterile corridor, conduct a 'time-out" with a member of the transplant team prior to leaving the donor OR to confirm that the correct organ is identified for the correct recipient prior to transplant. • Document the time-out in the EMR *Case Notes*. • Sign the organ in with the OR front desk. • Record the first and last name of the employee who received the organ along with the date and time in the EMR *Case Notes*. • The organ will be bagged IAW the applicable organ packaging policy and labeled IAW ***O 4.140 Labeling, Verification, Packaging, and Transport***, stored in a basin with ice, and covered with a sterile covering prior to being removed from the recovery suite.

h) Labeling Contingency Plan.

Responsible Person	Step	Action
Labeler	1	If TransNet is unavailable, complete ***O 4.140-2 Specimen Label*** and OPTN labels as necessary.
Verifier	2	A second individual will verify all handwritten labels when TransNet is unavailable.
[redacted]	3	The verification is documented in the EMR *Case Notes*.

6) Attachments.

a) O 4.140-2 Specimen Label.
b) O 4.140-7 Organ Packaging and Labeling Verification.
c) O 4.140-8 [redacted] Resources.
d) O 4.140-11 TransNet User Guide.

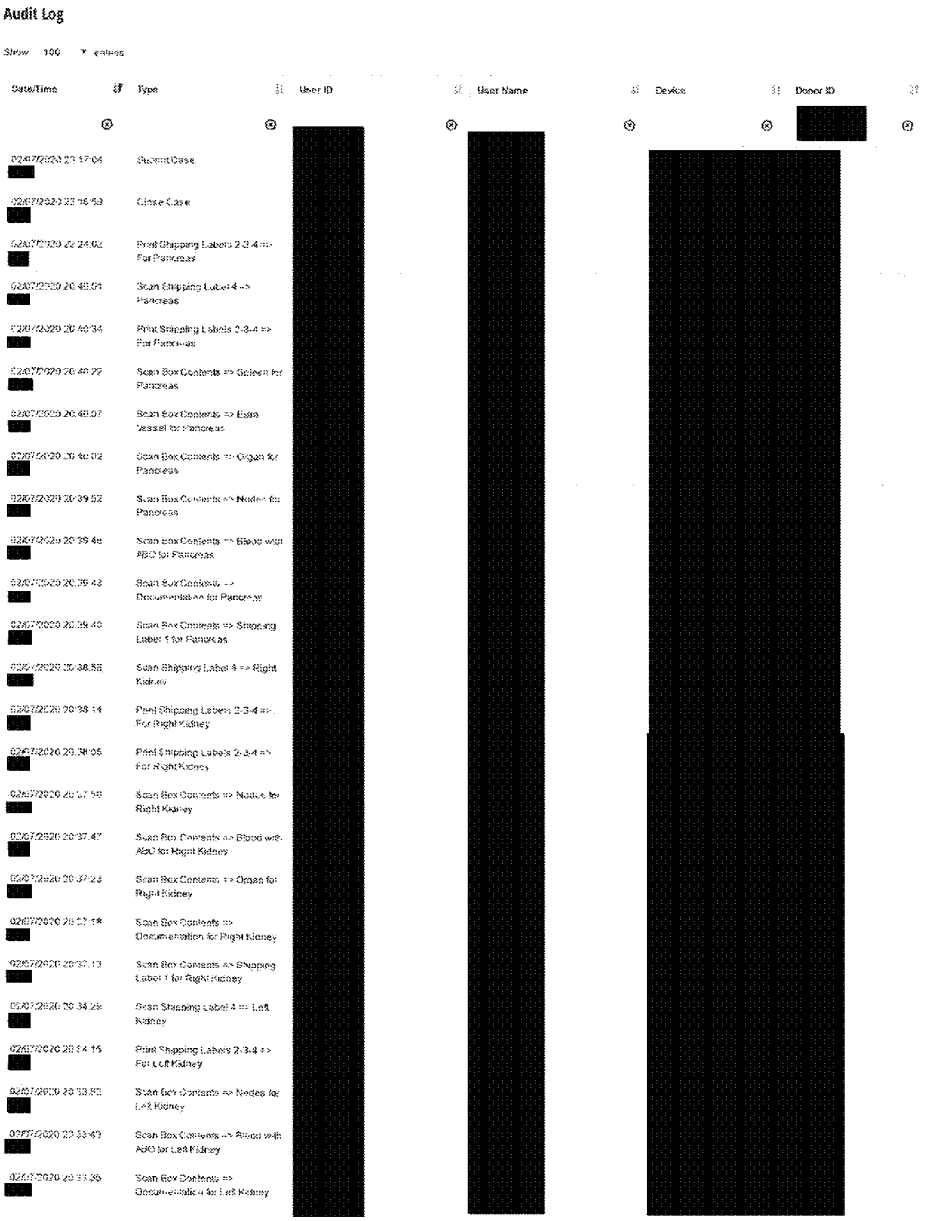
7) Referenced and Related Procedures.

a) L 21.000 Coroner/Autopsy Cases.
b) O 1.110 Specimens Drawn for Donor Evaluation.
c) O 2.080 Organ Donor Assessment, Evaluation and Maintenance.
d) O 4.130 Recovery of Tissue Typing Material.
e) O 5.210 Use of the LifePort Kidney Transporter.
f) Q 9.000 Labeling of Organs and Tissue Products.
g) S 3.000 Bloodborne Pathogens Policy.

8) Standards and Regulations.

a) Association of Organ Procurement Organizations (AOPO) Standards, CL 6.5 and SS 6.5.
b) Centers for Medicare and Medicaid Services (CMS) 42 CFR Chapter IV, § 486.346 (b-d).
c) OPTN Policies: 2.2(10), 16.2, 16.3, 16.4, 16.5, 16.6.

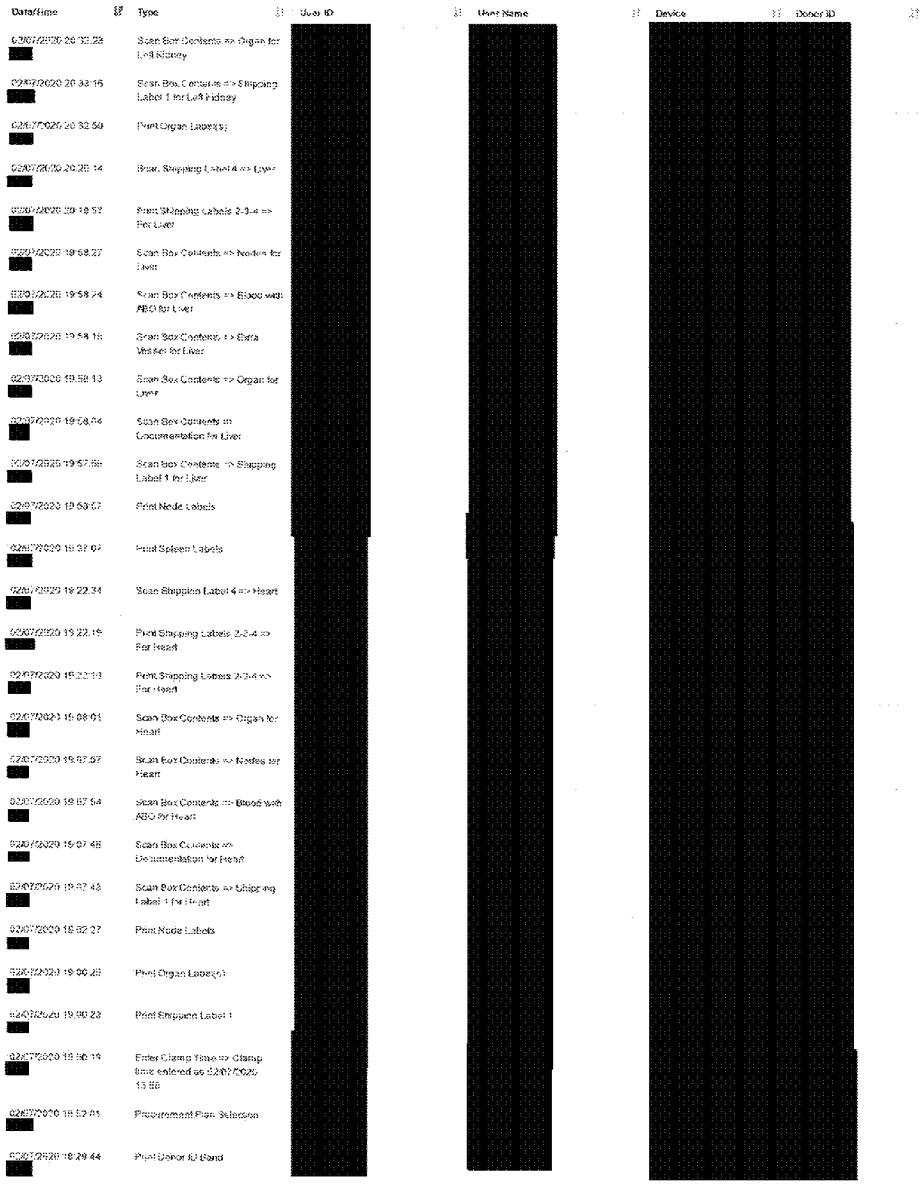
Appendix B



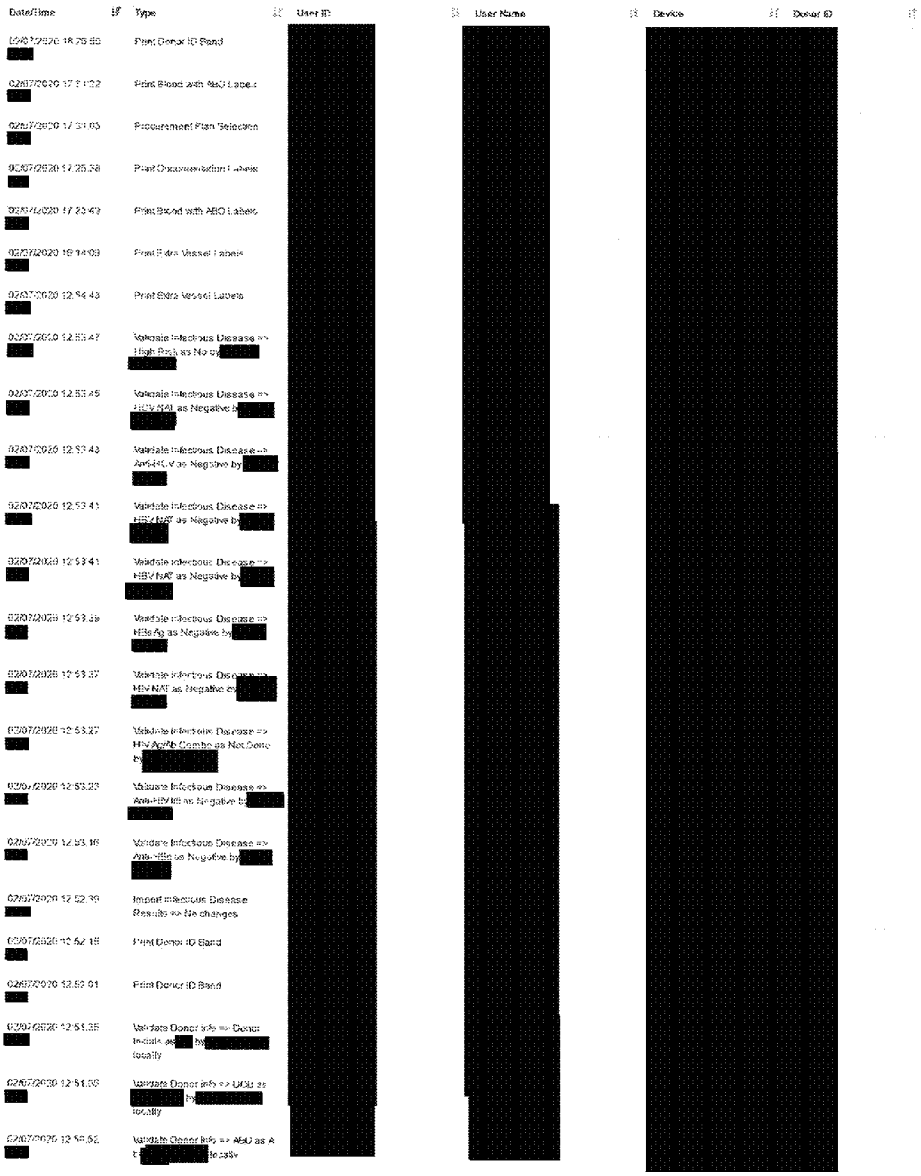
Audit Log

Show 100 entries

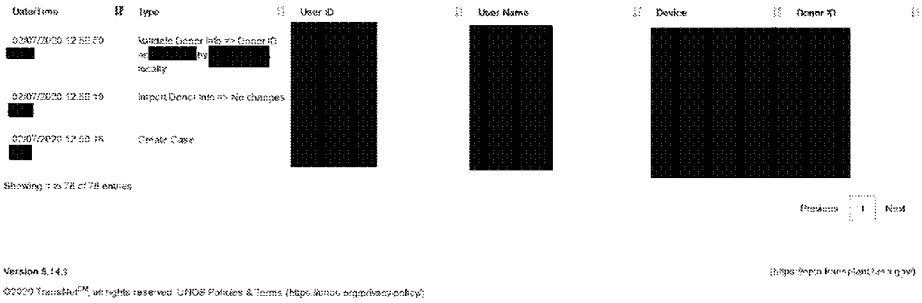
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[redacted]	Close Case	[redacted]	[redacted]	[redacted]	[redacted]
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[redacted]	Scan Box Contents => Extra Vessel for Pancreas	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	Scan Box Contents => Organ for Pancreas	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	Scan Box Contents => Nodes for Pancreas	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	Scan Box Contents => Blood with ABO for Pancreas	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	Scan Box Contents => Documentation for Pancreas	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	Scan Box Contents => Shipping Label 1 for Pancreas	[redacted]	[redacted]	[redacted]	[redacted]
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[redacted]	Print Shipping Labels 2-3-4 => For Right Kidney	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	Scan Box Contents => Nodes for Right Kidney	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	Scan Box Contents => Blood with ABO for Right Kidney	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	Scan Box Contents => Organ for Right Kidney	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	Scan Box Contents => Documentation for Right Kidney	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	Scan Box Contents => Shipping Label 1 for Right Kidney	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	Scan Shipping Label 4 => Left Kidney	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	Print Shipping Labels 2-3-4 => For Left Kidney	[redacted]	[redacted]	[redacted]	[redacted]
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Date/Time	Type	User ID	User Name	Device	Donor ID
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[redacted]	Scan Box Contents => Needles for Liver	[redacted]	[redacted]	[redacted]	[redacted]
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[redacted]	Procurement Plan Selection	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	Print Donor ID Band	[redacted]	[redacted]	[redacted]	[redacted]



Date/Time	Type	User ID	User Name	Device	Donor ID
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[redacted]	Print Blood with ABO Labels				
[redacted]	Procurement Plan Selection				
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[redacted]	Validate Infectious Disease => HBsAg as Negative by [redacted]				
[redacted]	Validate Infectious Disease => [redacted] as Negative by [redacted]				
[redacted]	Validate Infectious Disease => HIV Ag/Ab Combo as Not Done by [redacted]				
[redacted]	Validate Infectious Disease => Anti-HBc as Negative by [redacted]				
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[redacted]	Import Infectious Disease Results => No changes				
[redacted]	Print Donor ID Band				
[redacted]	Print Donor ID Band				
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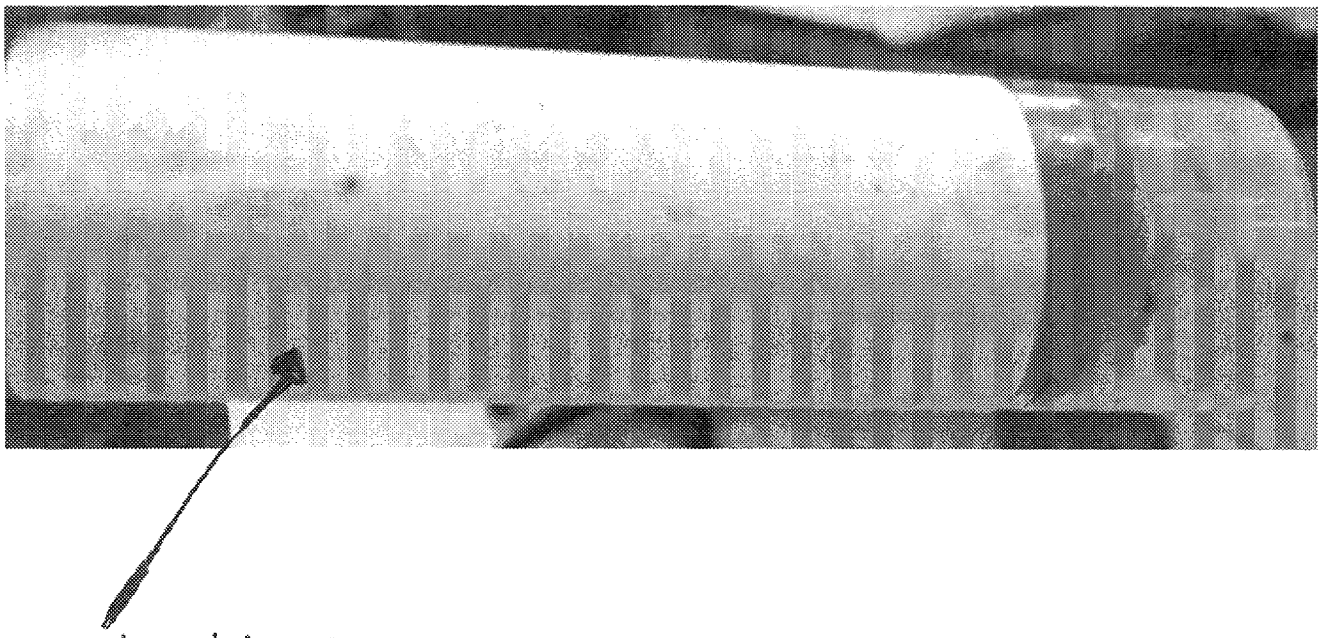
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Appendix C



[redacted]

3/5/2020



[redacted]

3/5/2020

From: [redacted]
To: [redacted]
Cc: [redacted]
Subject: FW: MPSC: Informal Discussion Offer
Date: Tuesday, January 22, 2019 1:23:42 PM
Attachments: [redacted] SCOP Informal Discussion Offer .pdf
Importance: High

Dear [redacted]

Thank you for your call today. Here is a summary of the items we discussed during our conversation.

- You asked if SCOP should present a slide deck for the informal discussion. I replied that you could submit any information that you want the MPSC to review in any format, but that it can be helpful for reviewers to refer back to information presented on a slide for reference.
- You discussed SCOP's search for additional information after this event (from blood banks and other sources). You voiced concern that this type of event may be a larger issue in the community. I stated that your presentation to the MPSC should primarily address the concerns stated in the Informal Discussion Offer letter and focus on the mitigating and corrective actions SCOP can take on its own to prevent recurrence of this event. Please save any larger community issues for the last minute(s) of the presentation or present this information separately prior to the discussion. If the MPSC feels that this issue is a larger community issue, they will address it as an educational referral to UNOS staff for further consideration.
- Feel free to ask MPSC reviewers for suggestions; they are your peers and they are available to you as a resource during the question and answer portion of the informal discussion.
- I stated that I believe with 90% certainty that the informal discussion will be on held on Monday, January 28th in the afternoon. Please arrange for OPO staff to be available for the discussion if possible. There will be more instructions in the scheduling letter coming tomorrow.

Feel free to reach out if you have any additional questions or concerns.

Kind regards,

[redacted]
Compliance Operations Analyst
Member Quality

UNOS UNITED NETWORK FOR ORGAN SHARING

Matching organs. Saving lives.

[redacted]

From: [redacted]@unos.org>
Sent: Tuesday, January 22, 2019 11:38 AM
To: [redacted]@sharinghopesc.org>
Cc: [redacted]@unos.org>
Subject: MPSC: Informal Discussion Offer
Importance: High

[redacted]

This email is your notice that I have received your written acceptance of the MPSC's Informal Discussion offer. I have attached the Informal Discussion Offer letter you requested, sent via regular email so you can open it while traveling. There is nothing else I need from you today. The information requested from the MPSC in the letter can be presented during your portion of the informal discussion or sent earlier for MPSC review if you would like to use your presentation time for other material.

Sometime tomorrow, I will be sending you a scheduling letter and a document providing a high-level overview of what to expect when preparing for an informal discussion. Let me know if you have any questions.

Kind regards,

[redacted]
Compliance Operations Analyst
Member Quality

UNOS UNITED NETWORK FOR ORGAN SHARING

Matching organs. Saving lives.

[redacted]

[redacted]

UNOS
UNITED NETWORK FOR ORGAN SHARING
Matching organs. Saving lives.

CONFIDENTIAL MEDICAL PEER REVIEW

January 18, 2019

VIA SECURE EMAIL

[redacted]
CEO/President
OPTN/UNOS Representative
We Are Sharing Hope SC
[redacted]

[redacted]
Medical Director, Organ Division
We Are Sharing Hope SC
[redacted]

Dear [redacted]:

As you know, UNOS' Member Quality Department staff has been reviewing the blood typing and transplant of incompatible organs from donor [redacted]. The Membership and Professional Standards Committee (MPSC) leadership, including the Vice Chair, Chair of the Performance Analysis and Improvement Subcommittee (PAIS), and Chair of the Policy Compliance Subcommittee (PCSC), along with the OPTN President are reviewing the information that We are Sharing Hope SC (SCOP) has submitted to this date, in a blinded fashion. The leadership group has requested additional specific information and requested that the program participate in an informal discussion to discuss this case.

In order to facilitate a dialogue and for the MPSC to better evaluate the issue, the Committee leadership requests that SCOP participate in an informal discussion with the MPSC. This informal discussion will take place via conference call. UNOS staff will work to set up the call as soon as possible.

MPSC Concerns

The MPSC leadership was concerned by the failure of SCOP's staff and AOC to recognize the potential safety consequences of indeterminate blood typing issues. The group was concerned with the use of broad terminology such as mass transfusion and indeterminate blood type instead of firm clinical and situational triggers when determining which donor cases go for AOC and Medical Director review. Finally, the group was particularly concerned that SCOP did not

[redacted]

[redacted]
We Are Sharing Hope SC
January 28, 2019
Page 2

CONFIDENTIAL MEDICAL PEER REVIEW

accept responsibility for this event and look internally to assess what OPO staff could have done to prevent this event, regardless of the actions of the donor hospital.

In an effort to mitigate the risk to patient health and public safety, the MPSC requested that SCOP immediately do the following:

- For every donor with a blood typing sample that is hemodiluted for the primary or confirmatory draw, the OPO must:
  - Send the case to the AOC and Medical Director for review prior to assigning ABO
  - Communicate to all receiving transplant centers that the ABO has been determined using a hemodiluted sample
- Using defined clinical triggers, develop an event-driven algorithm that will automatically prompt mass transfusion cases for review by the AOC and Medical Director.

These actions must be completed until an MPSC-approved protocol is in place.

The MPSC has also requested that SCOP submit the following documentation:

- An updated RCA that includes a comprehensive internal assessment of actions the OPO could have taken to prevent this type of event
- An updated corrective action plan that includes policy development and staff and leadership training regarding mass transfusions and ABO typing.

Informal Discussion Timelines

Informal discussions are described in Appendix L of the Bylaws, which can be accessed on the OPTN website at http://optn.transplant.hrsa.gov. Informal discussions are intended to provide the MPSC and member an opportunity to openly discuss the review and seek feedback. If your institution wishes to participate in the informal discussion, please submit written notification to [redacted] Compliance Operations Analyst no later than **Tuesday, January 22, 2019**, to [redacted]

The informal discussion schedule will include 10 minutes for your presentation and 15 minutes for a question and answer period with the MPSC. After the call, the group will report its recommendation to the MPSC. We will notify you of the outcome as soon as possible after the MPSC's deliberations.

Please submit any additional documentation you would like the participants to review prior to the informal discussion as soon as possible. The MPSC will provide a deadline for additional documentation after the call.

Please be aware that this correspondence and all related documents and information are protected by applicable peer review statutes. Members must keep all information provided in the medical peer review processes and settings confidential. Therefore, all inquiries, deliberations, recommendations, and actions of the MPSC, Board of Directors, other committees, and Organ Review Boards must be kept confidential by members during the review process and after the matter is closed. The Board of Directors may make public certain final adverse actions as outlined in the Bylaws.

[redacted]

CONFIDENTIAL MEDICAL PEER REVIEW

If you have any questions or concerns, or need any additional information regarding this issue, please contact [redacted]

Sincerely,

[redacted]

Vice Chair, OPTN/UNOS Membership and Professional Standards Committee

[redacted]

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

					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?

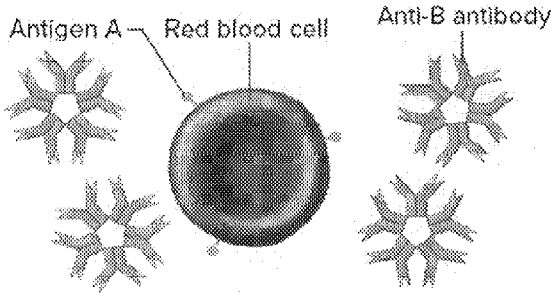
ABO TYPING

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

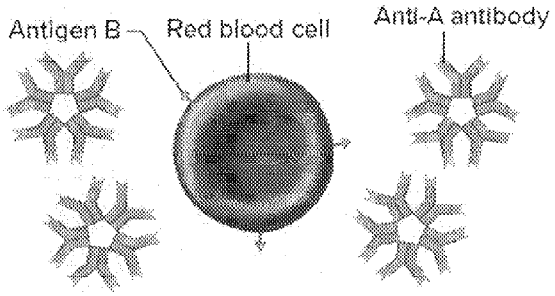
·Forward Typing- this test is used to detect the presence or absence of A and/or B antigens on ***red blood cells***. ABO group is *determined*.

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

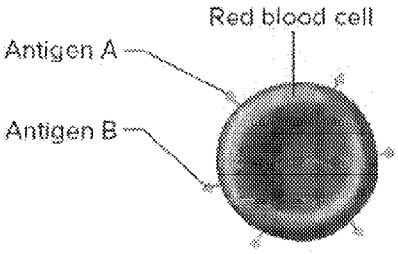
·D typing not relevant to transplantation.



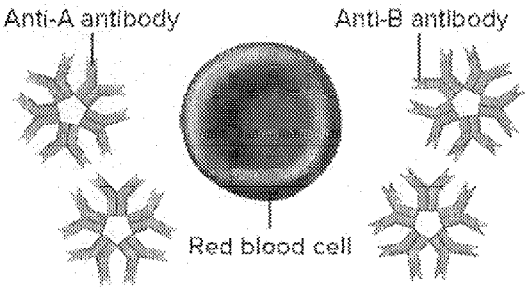
Type A blood



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".

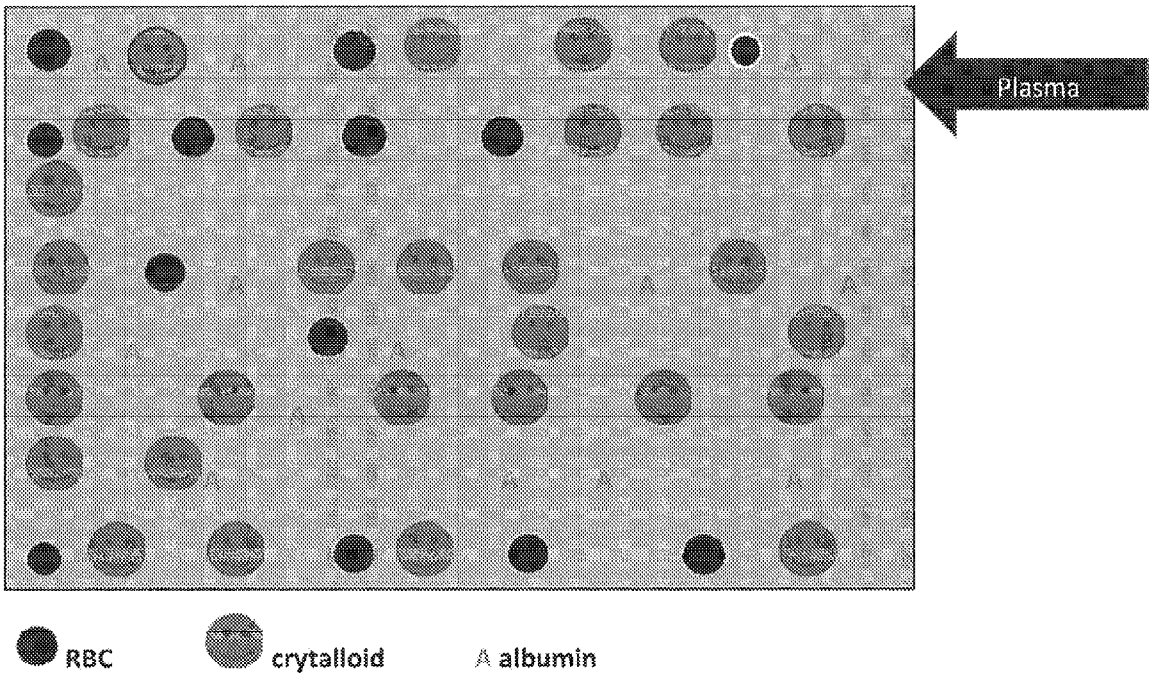
There are 2 ways to become hemodiluted:

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.

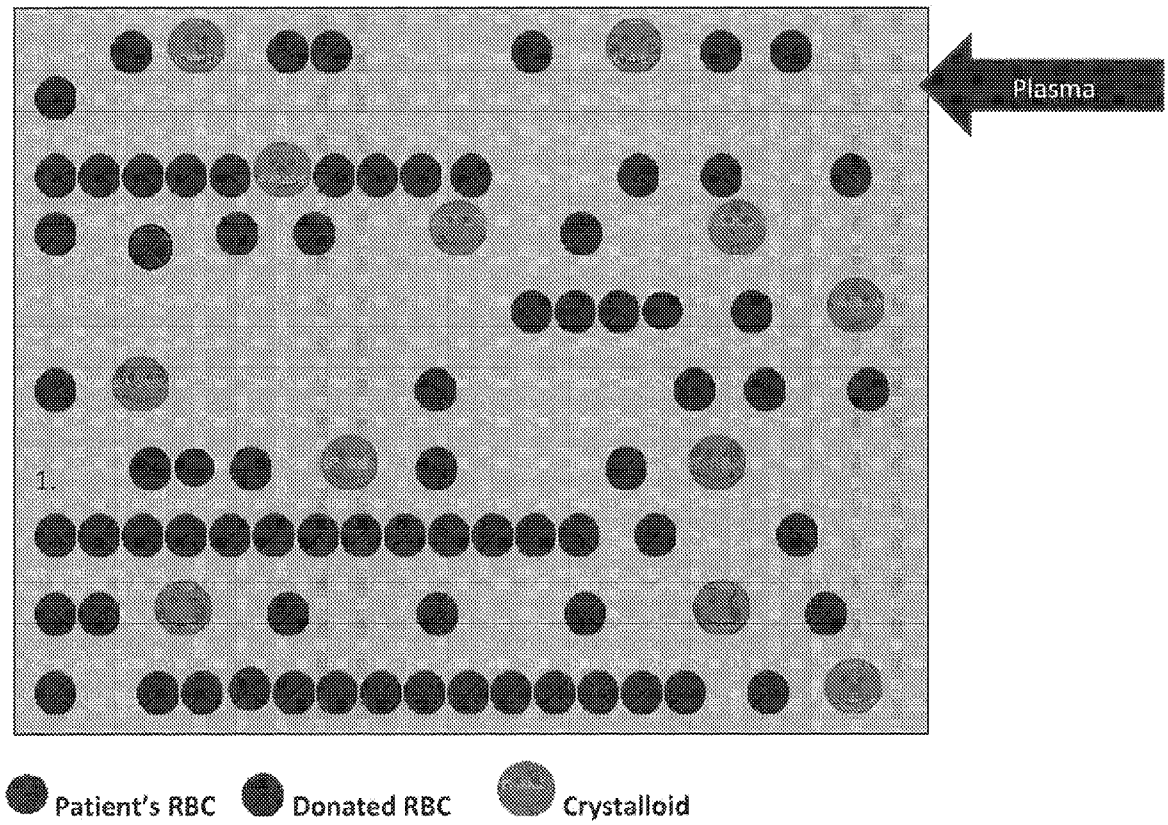
2. Massive blood product transfusion. The ratio of donated blood cells and/or plasma is greater than the patient's own blood volume and circulating blood cells.

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 <u>any</u> 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 *<u>hemodiluted</u>*. 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 <u>for this ABO only</u>.*

☐ 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]

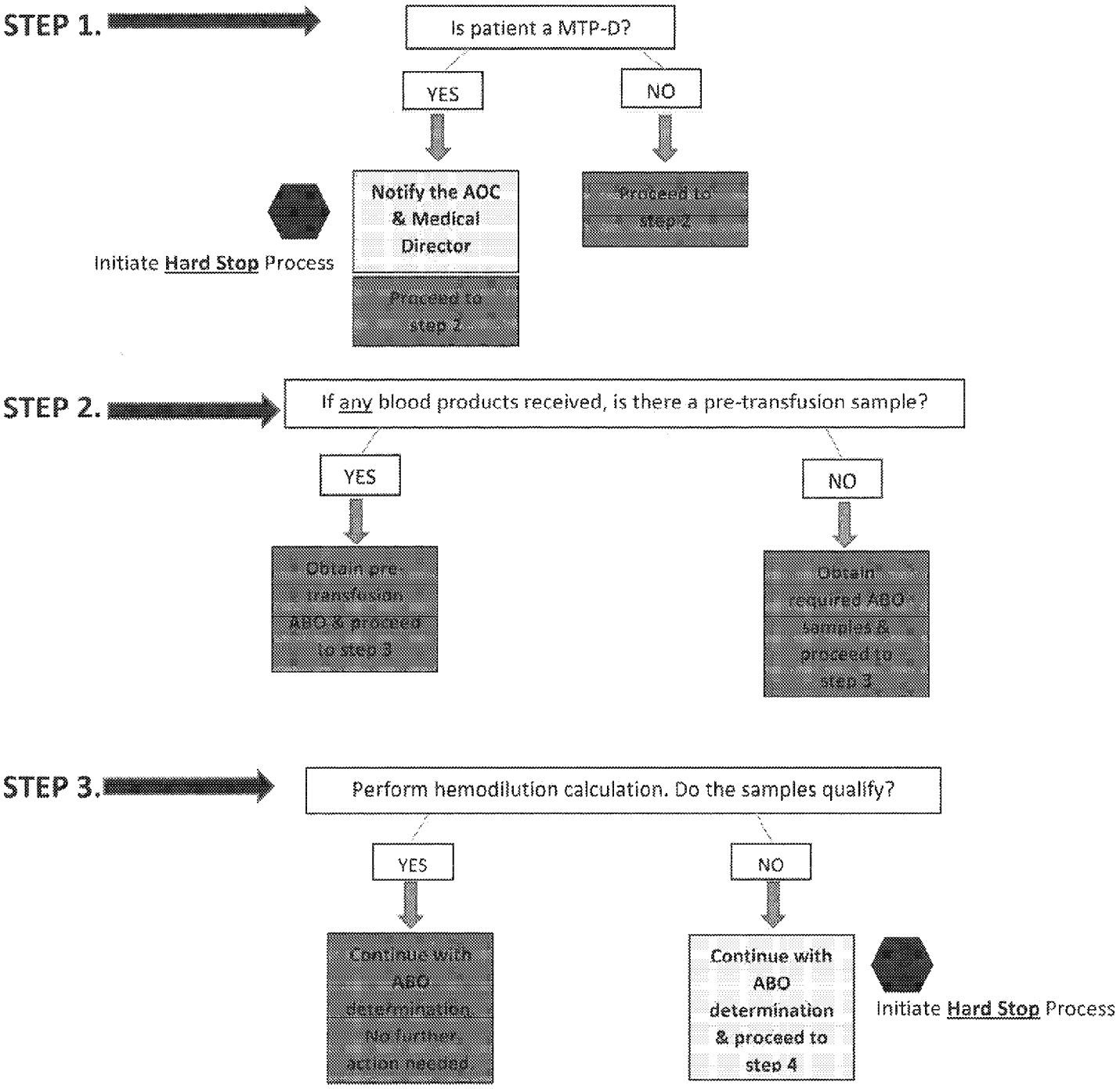
ABO Results Process Map

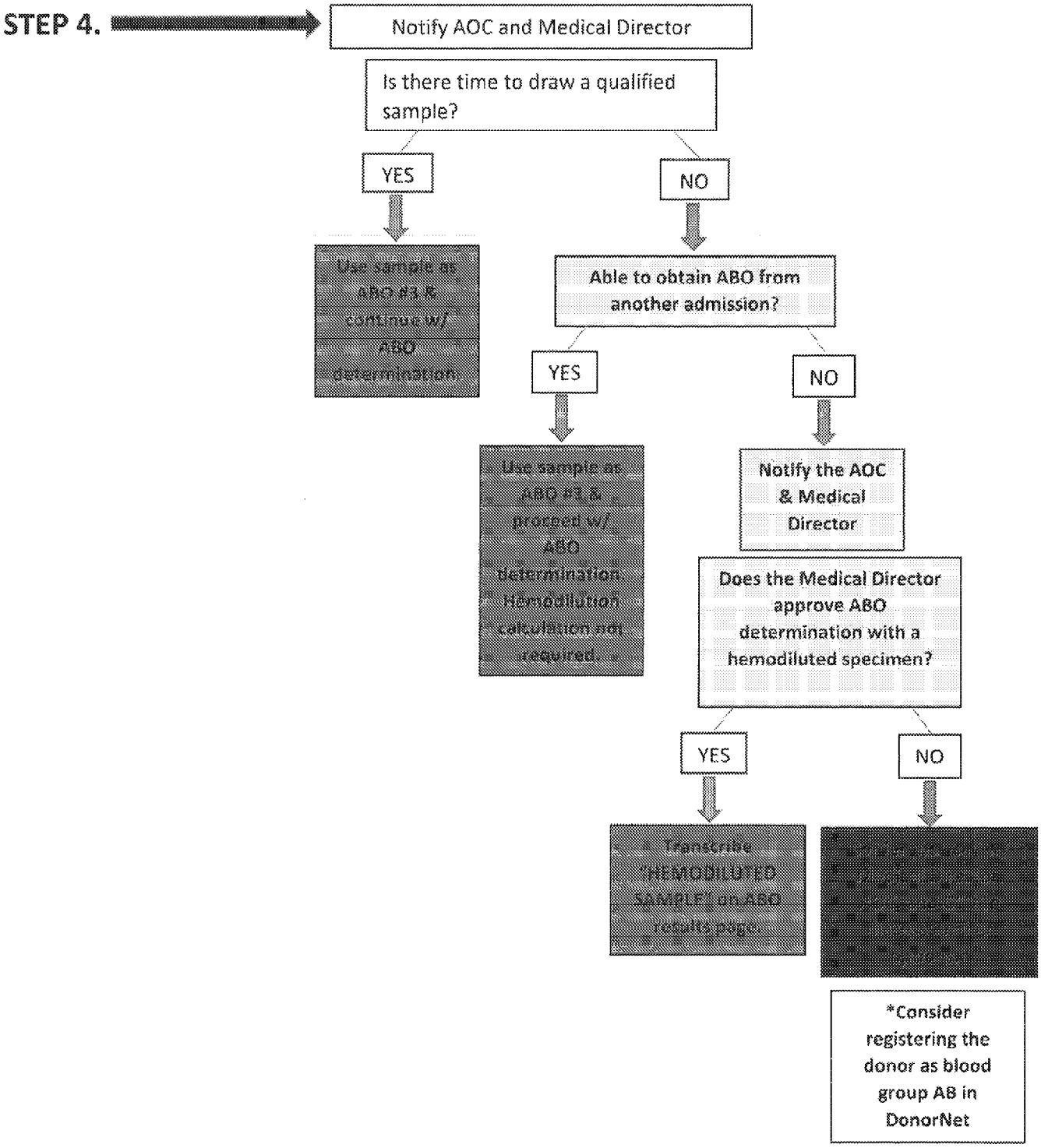
1. **Any ABO Results Indeterminate**
   No – [Proceed with Donation]
   Yes – [Notify AOC and Medical Director] [OPO MUST re-run another ABO x 2]

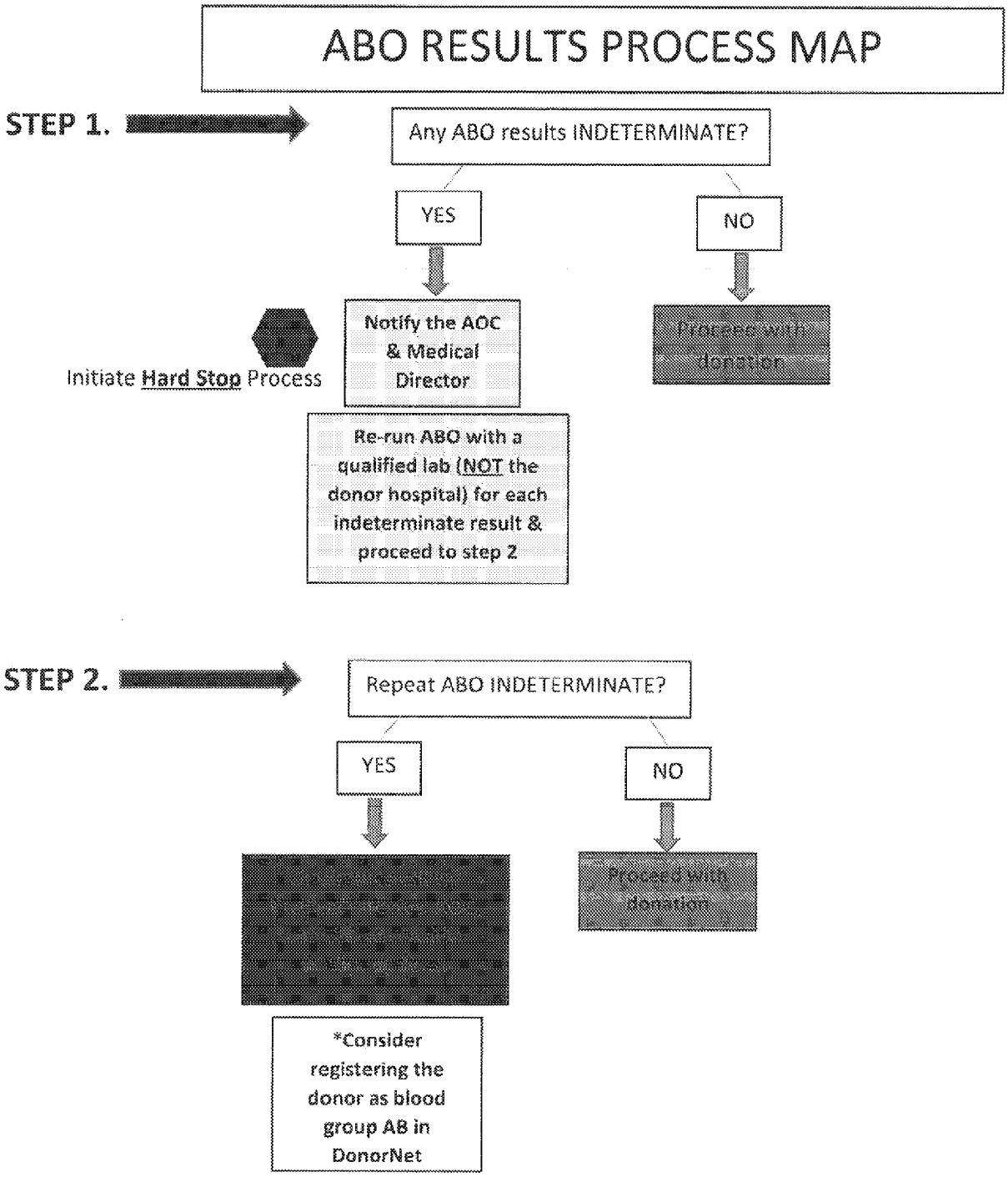
2. **Repeat ABO result is Indeterminate**
   No – [Proceed with Donation]
   Yes – [Notify AOC and Medical Director]

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.

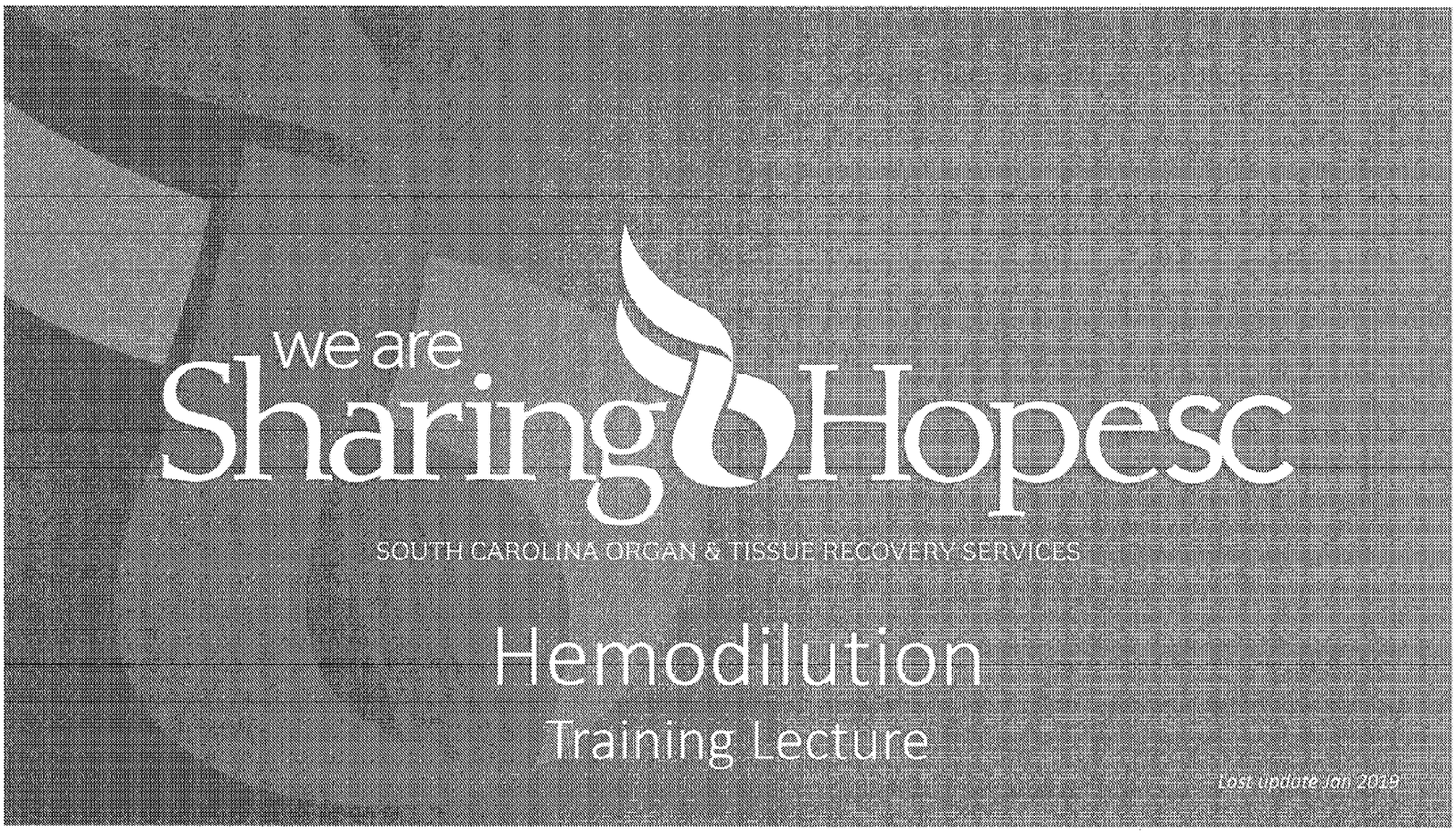
This form has been reviewed by the representative of the accepting transplant center. ALL signatures must be received from the accepting transplant center before the OR time can be set for organ recovery.

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)(i) 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.			

[redacted]

UNOS
UNITED NETWORK FOR ORGAN SHARING
Matching organs. Saving lives.

CONFIDENTIAL MEDICAL PEER REVIEW

March 13, 2019

VIA SECURE EMAIL

[redacted]
CEO/President
OPTN/UNOS Representative
We Are Sharing Hope SC
[redacted]

[redacted]
Medical Director, Organ Division
We Are Sharing Hope SC
[redacted]

Dear [redacted]

As you know, Membership and Professional Standards Committee (MPSC) leadership, including the Vice Chair, Chair of the Performance Analysis and Improvement Subcommittee (PAIS), and Chair of the Policy Compliance Subcommittee (PCSC), along with the OPTN President reviewed We are Sharing Hope's (SCOP) root cause analysis, containment plan and corrective actions regarding donor [redacted]'s ABO determination that led to incompatible transplants. After this review, the leadership group requested additional specific information and requested that the program participate in an informal discussion to discuss this case.

SCOP participated in an informal discussion on January 28, 2019 with an MPSC subcommittee. The MPSC met on February 27, 2019, and reviewed submitted documentation and the subcommittee's recommendations.

Based on its review, the MPSC approved the following:

> RESOLVED, that the Membership and Professional Standards Committee issues a Notice of Noncompliance to We are Sharing Hope for violation of Policy 2.6.A (Deceased Donor Blood Type Determination).

The Committee voted 29 For; 0 Against; and 1 Abstention.

[redacted]

[redacted]
We Are Sharing Hope SC
March 13, 2019
Page 2

CONFIDENTIAL MEDICAL PEER REVIEW

The MPSC also requests that SCOP submit the following documentation for MPSC review:

- A log of all cases escalated for Medical Director review identifying:
  - The trigger that escalates the case for review
  - Steps taken by the AOC and Medical Director to resolve the case
  - The case resolution

The MPSC also suggests that SCOP consider looking at additional cases of unexpected graft failure. SCOP may want to look at those cases, even if they did not meet their criteria for review, to determine whether they may also have blood type determination issues. Please submit the requested documentation to [redacted] Compliance Operations Analyst, no later than **May 23, 2019**.

Pursuant to the above resolution, the MPSC hereby issues this Notice of Noncompliance to SCOP.

Please note, a Notice of Noncompliance is included in Appendix L of the Bylaws, which is accessible at http://optn.transplant.hrsa.gov. A Notice of Noncompliance is not an adverse action under the Bylaws but is meant to inform the member of the need to ensure continuing compliance with policies monitored by UNOS. A Notice of Noncompliance does not need approval from the Board of Directors and is not made public. UNOS will include the letter in your member compliance history, and it may be considered by the MPSC should future compliance issues arise.

Please be aware that this correspondence and all related documents and information are protected by applicable peer review statutes. Members must keep all information provided in the medical peer review processes and settings confidential. Therefore, all inquiries, deliberations, recommendations, and actions of the MPSC, Board of Directors, other committees, and Organ Review Boards must be kept confidential by members during the review process and after the matter is closed. The Board of Directors may make public certain final adverse actions as outlined in the Bylaws.

If you have any questions or concerns, or need any additional information regarding this resolution, please contact [redacted]

Sincerely,

[redacted]
Vice Chair, OPTN/UNOS Membership and Professional Standards Committee

[redacted]

UNOS MPSC Presentation

Donor ID [redacted]

ABO Incompatibility Event

Admission and Donation Course

11/24/2019 @ 21:08

- 24 y/o female admitted s/p motorcycle accident with multi-system organ trauma – liver laceration, multiple fractures, CHI. Transfusions started immediately upon arrival in the ED.

11/25/2019 @ 16:34

- Pt was declared brain dead with clinical exam and apnea testing

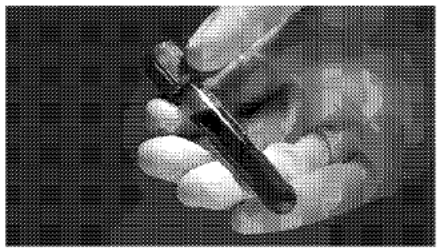
11/25/2019 @ 18:50

- SHSC obtained authorization for donation and assumed care of the patient



ABO Determination – *What We Saw*

- SHSC begins process of ABO determination & donor care
  - No Pre-transfusion sample available – Sample hemolyzed
  - 11/24/2019 @ 2309 **Hospital** ABO # 1 resulted as **Blood Group O**
  - 11/25/2019 @ 1900 – **SHSC** ABO # 2 resulted as **Indeterminate**
    - ***Forward 0 Reverse A***
- ***Now what?***



ABO Determination – *What We Did*

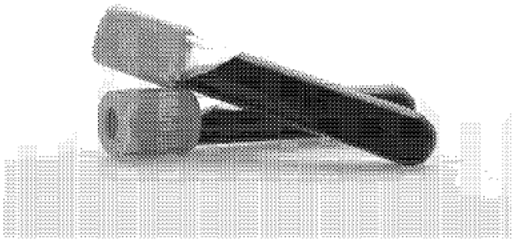
- SHSC staff escalates the Indeterminate Result to the AOC.
- SHSC AOC decision is to re-run the ABO or find another hospital result with a different draw date and time.
  - No escalation to the Medical Director
- SHSC Coordinator finds another hospital ABO result.
  - The hospital's blood bank requested an ABO after the patient's name change.

- 11/25/2019 @ 1950 – Hospital ABO # 3 resulted as **Blood Group O.**

ABO Determination – *What We Saw*

- **Hospital ABO # 1** resulted as **Blood Group O.**
- **SHSC ABO # 2** resulted as **Indeterminate.**
- **Hospital ABO # 3** resulted as **Blood Group O.**

- **ABO # 3 verifies ABO # 1**

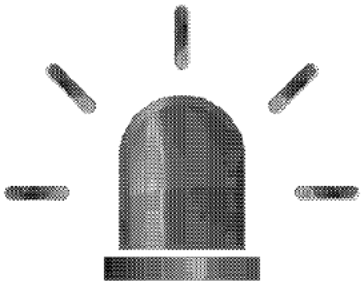


ABO Determination – *When We Knew*

- 11/28/2019 @ 00:52
  - Pancreas transplant center notifies SHSC that their confirmatory testing is showing Blood Group A.
  - SHSC AOC notifies transplant centers of this finding.
    - Thoracic transplant recipients deteriorating.
    - Abdominal transplant recipients are ok.
  - SHSC halts pancreas and one kidney transplant.
  - SHSC requests ABO typing by MUSC Blood Bank.
    - MUSC uses sample obtained at the time of the OR.
  - **Donor ABO is Blood Group A**

Sentinel Event – *What We Did*

- Sentinel Event – Emergency meeting of leadership team.
  - Developed our investigation & response plan with the team.
  - Conducted literature search for any standards/guidelines regarding hemodilution and ABO determination.
  - Immediate chart review with senior recovery leadership to identify gaps and/or process and policy errors.



Sentinel Event – Immediate Containment Plan

- Immediate Containment Plan
  - ANY indeterminate ABO result immediately escalated to the Medical Director for review.
  - Consider any Indeterminate ABO result a HARD STOP until Medical Director discussion and resolution.



Sentinel Event – *What We Did*
Education & Notification

- Contacted Director of the MUSC Blood Bank to review the event.
  - Discussed Forward and Reverse Typing results.
  - Discussed potential future testing possibilities i.e., molecular testing.
  - Requested any standards/guidelines for ABO determination in the presence of hemodilution.
- Contacted **Medical Director(s)** and **AOC(s)** staff to review containment plan and educate on Forward and Reverse Typing.
- Reported to UNOS



Sentinel Event – *What We Did*
Education & Notification

- Discussed this case with clinical staff and discussed the impact of ABO incompatibility transplants.
  - Clinical Donation Coordinators (CDC)
  - Clinical Allocation technicians (CAT)
- Reviewed Containment Plan with CDC and CAT staff.
- Notified UNOS of the Containment Plan.



Sentinel Event – *What We Did*
Root Cause Analysis

- Continued the RCA to establish root cause of the event.
  - **SHSC & MUSC Blood Bank Meeting**
    - Reviewed case with the Director of MUSC Blood Bank to obtain expert opinion on potential gaps and/or process improvements in ABO determination in massive transfusions.
    - Assessed availability of any standards and guidelines for ABO Determination in Hemodilution or Massive Transfusion Protocols.
    - Reviewed and confirmed understanding of "Forward and Reverse typing."
  - **SHSC & Donor Hospital Meeting**
    - Reviewed ABO testing practices and policy guidelines with donor hospital.



Sentinel Event – *What We Did*
Process & Policy Development

- Developed new processes and guidelines:
  - **SHSC Hard Stop Process**
    - HARD STOP in the event of ANY indeterminate ABO result.
    - Escalation to AOC and Medical Director.
    - OPO must re-run another ABO in order to verify.



  - **ABO Determination & Hemodilution Playbook**
    - SHSC definition of Massive Transfusion Protocol for SHSC Donors.
    - Require ABO performed on pre-transfusion sample (when available).
    - Qualify samples used for ABO determination.
    - Develop **Worksheet** to guide clinical staff in the new process.
  - **Donor ABO Algorithm**
    - Process map for identifying & resolving ABO determination in hemodilution and massive transfusion protocols.



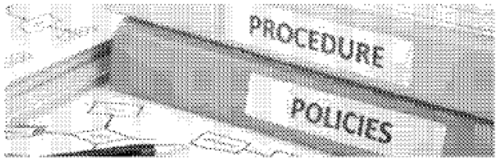
Sentinel Event – *What We Did*
Staff Training & Education

- Acute and ongoing training resulting from the Sentinel Event.
- **Completed**
  - SHSC Containment Plan
  - Hard Stop Process
  - ABO Determination & Hemodilution Playbook
  - Medical Directors and AOCs – Forward and Reverse Typing
- **Pending**
  - Lunch & Learn with [redacted] – MUSC Blood Bank
    - ABO Determination and the Impact of Transfusions
  - ABO Determination & Hemodilution Algorithm
- Plans to enhance our standard introductory clinical training to include this event.



Sentinel Event – *What We Did*
Policy Revision

- Ongoing policy revision to include these new and enhanced processed.





Thank You

ABO Determination

Membership and Professional Standards Committee
February 26-27, 2019
[redacted]
Compliance Operations Analyst

OPTN | UNOS

Overview

- Two cases in this cycle regarding ABO determination in donors who received massive transfusions
- One case went through the standard PCSC review process
- Other case went through MPSC Leadership pathway that led to an informal discussion
- Review for similarities and differences, determine an action for each case
- Results of preliminary UNOS data search

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Relevant Policy

- **2.6.A Deceased Donor Blood Type Determination and Reporting**

  The host OPO must ensure that each deceased donor's blood type is determined by testing at least two donor blood samples prior to the match run. The host OPO must develop and comply with a written protocol to resolve conflicting primary blood type results.

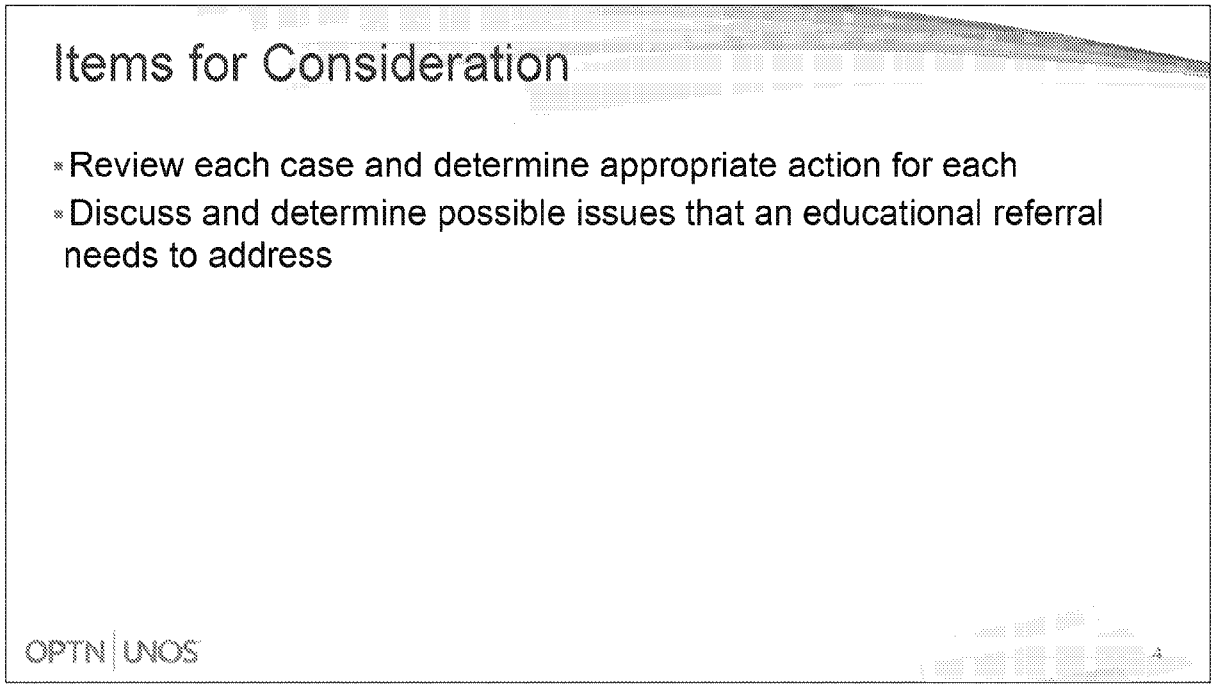
  Deceased donor blood samples must:

  1. Be drawn on two separate occasions
  2. Have different collection times
  3. Be submitted as separate samples
  4. Have results indicating the same blood type

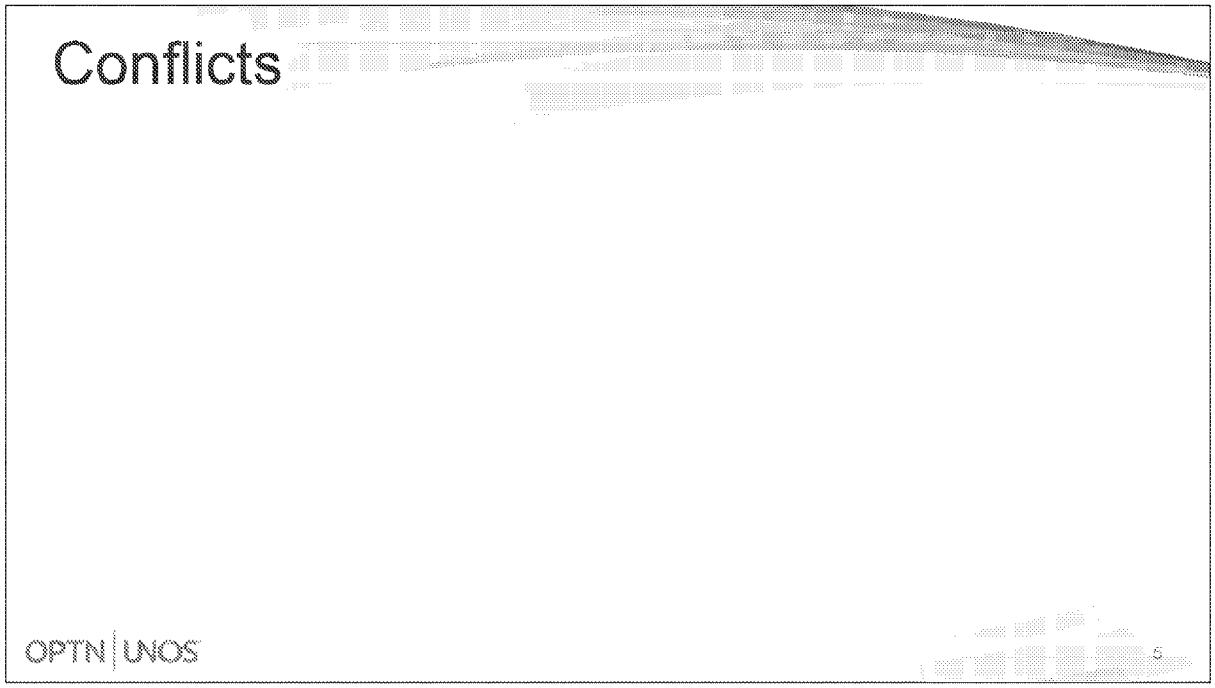
  The host OPO must document that blood type determination was conducted according to the OPO's protocol and the above requirements.

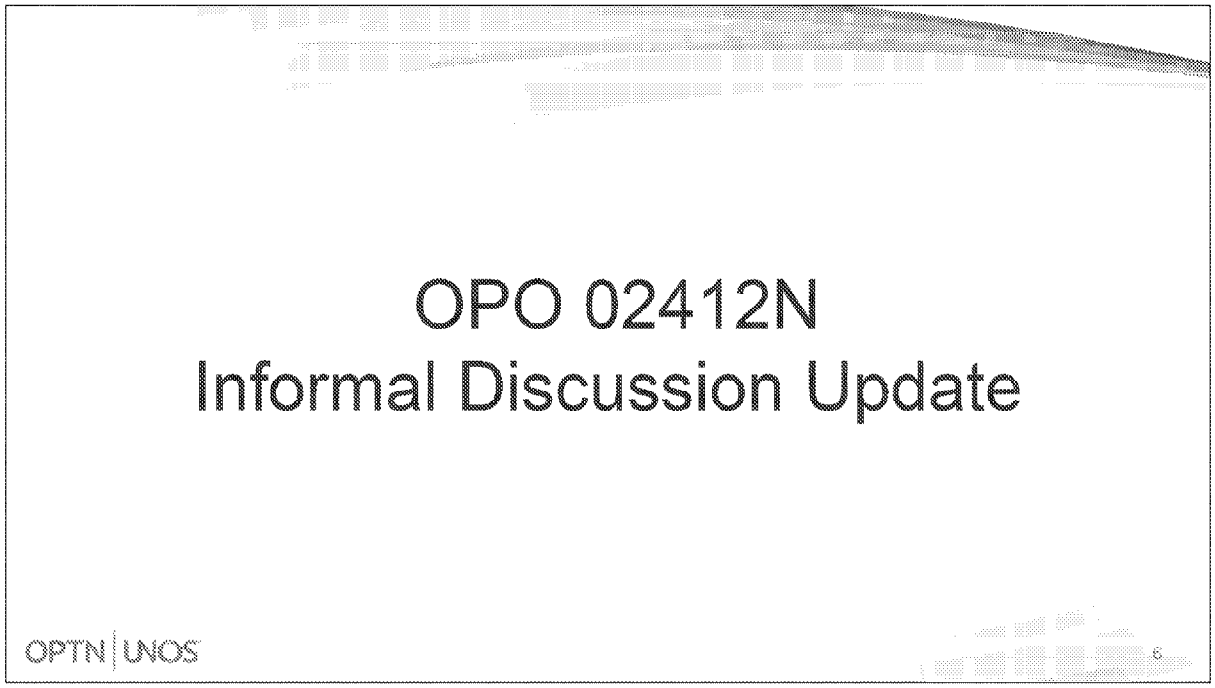
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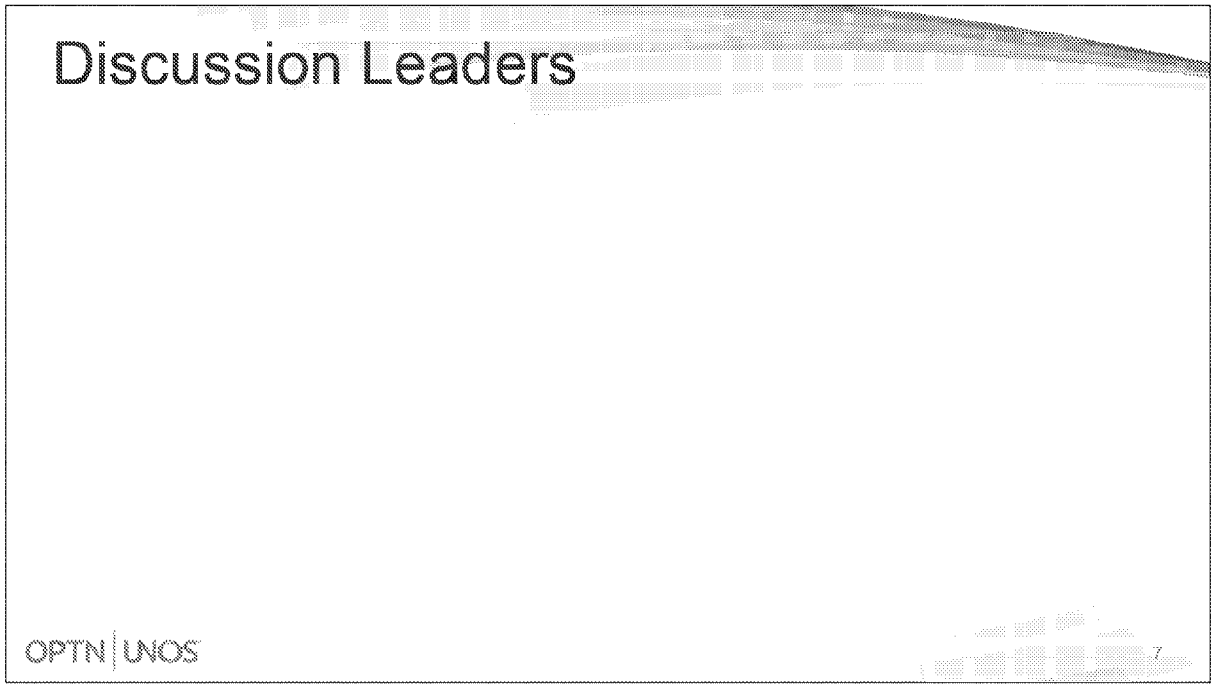
3



Actions can be different if the situation or member response is different, but otherwise the MPSC should be as consistent as possible .


Conflicts
OPTN | UNOS


OPO 02412N
Informal Discussion Update
OPTN | UNOS
6


Discussion Leaders
OPTN | UNOS
7

Case Overview

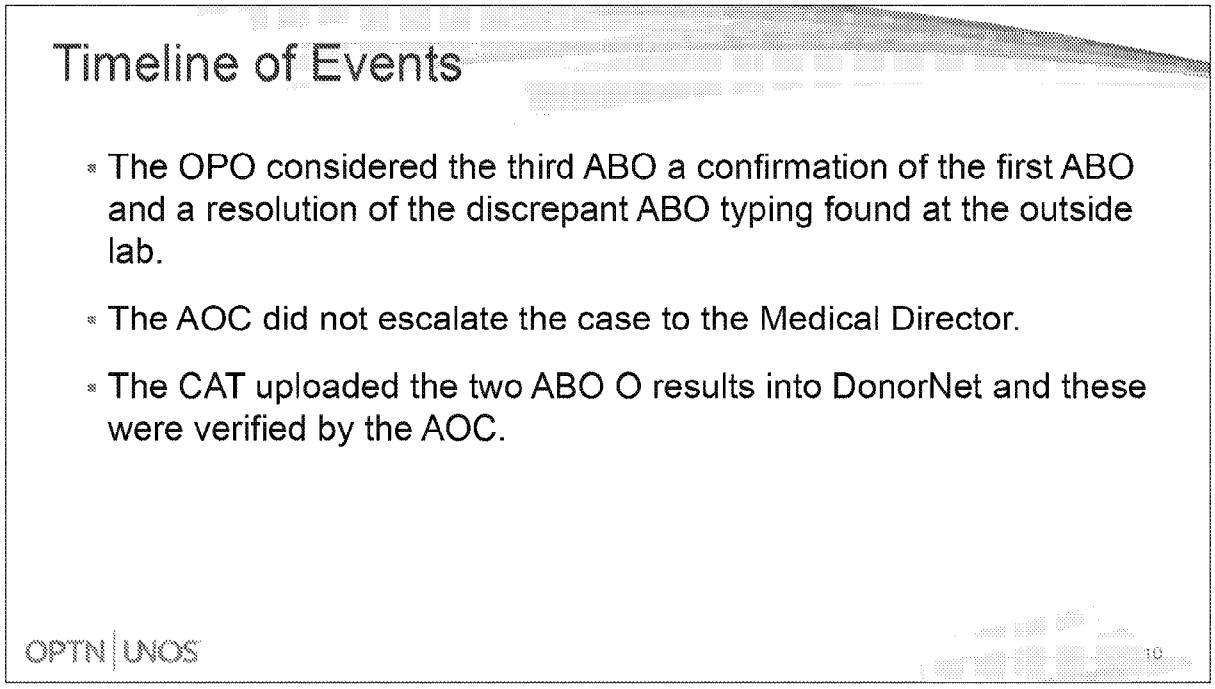
- In late November, OPO reported an incorrect ABO typing that resulted in incompatible organ transplants leading to two organ discards and one recipient death. MPSC held an informal discussion to discuss the member's root cause analysis and corrective actions regarding this event.
- 24 y/o female, motor cycle vs. tree with head trauma. The donor was 5' 6" tall and weighed 130 pounds, resulting in an estimated total plasma volume of 2356 ml and an estimated total blood volume of 3926 ml.
- Massive transfusions of 12 units of PRBC, 10 units of FFP, and 3 units of platelets resulted in administration of 3700 ml of plasma products and 3000 ml of blood products.
- Pre-transfusion blood drawn at admission was hemolyzed and unable to be used for ABO typing.

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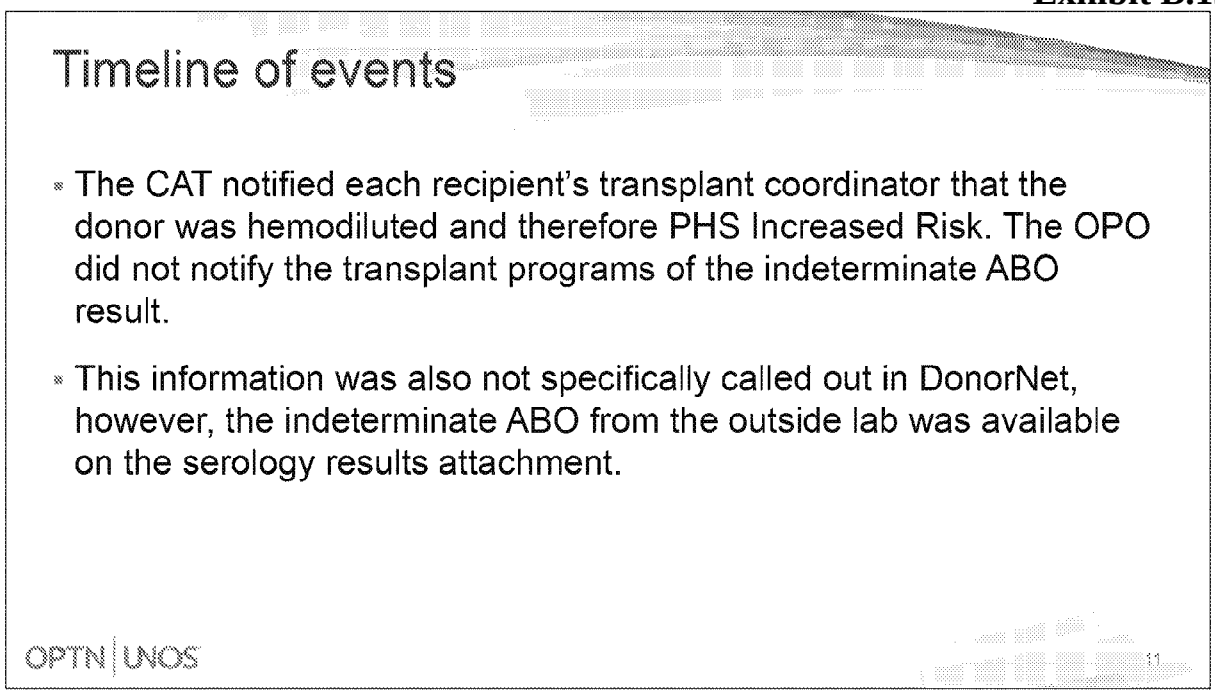
ABO typing

Sample	Location	Result	Reported
Admission	Donor Hospital	Indeterminate	Hemolyzed
ABO #1	Donor Hospital	ABO O Fwd O, Rev A	O
ABO #2	Serology Lab	Indeterminate Fwd O, Rev A	Indeterminate
ABO #3	Donor Hospital	ABO O Fwd O, Rev O	O
OR Sample	OPO's Local Hospital	ABO A Fwd A, Rev A	A

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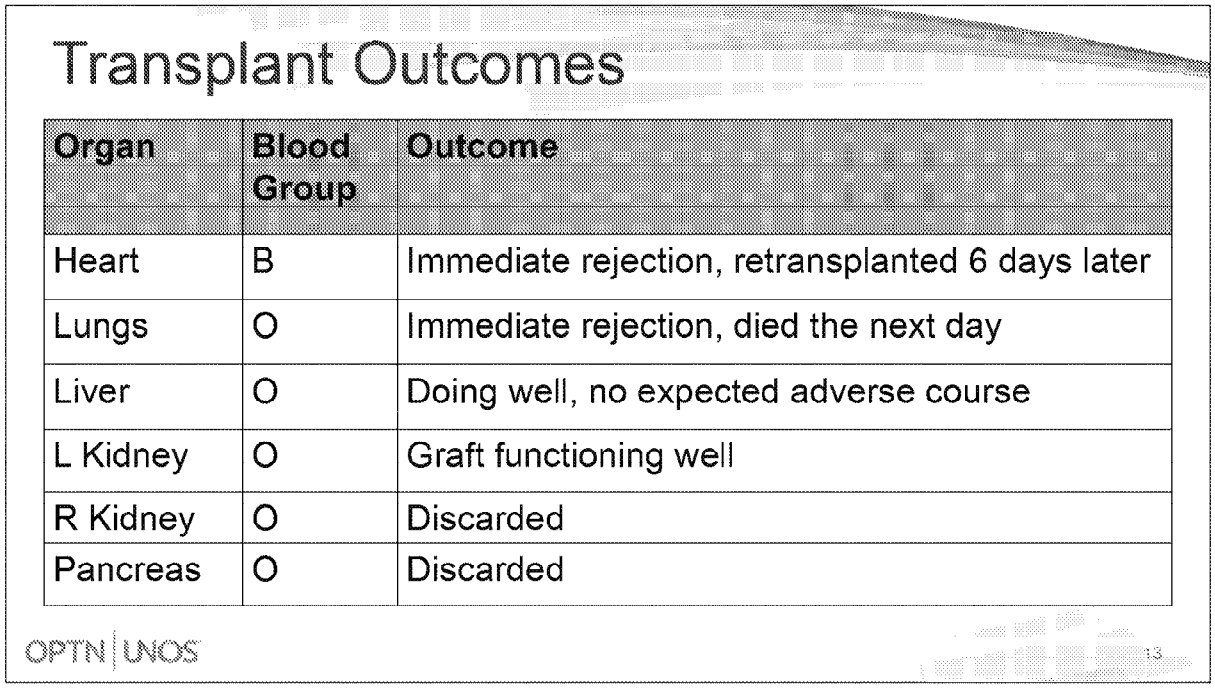
CAT- Clinical Allocation Technician



CAT – Clinical Allocation Technician

Timeline of events

- The day after procurement, the pancreas program contacted the OPO to alert them that the blood sent with the pancreas resulted in ABO A.
- The OPO then alerted the other receiving centers, but the heart, lungs, liver, and left kidney had already been transplanted.
- All receiving centers and the OPO reported this event through the OPTN Improving Patient Safety Portal.



Hospital 41473N received the heart and transplanted it into an ABO B recipient. After release of crossclamp, the heart stiffened and became edematous. Hospital 41473N was unable to get the recipient off of CPB, and converted to VA ECMO. After six days the heart recipient was retransplanted.

The heart recipient is doing well and was discharged home 22 days after the second transplant.

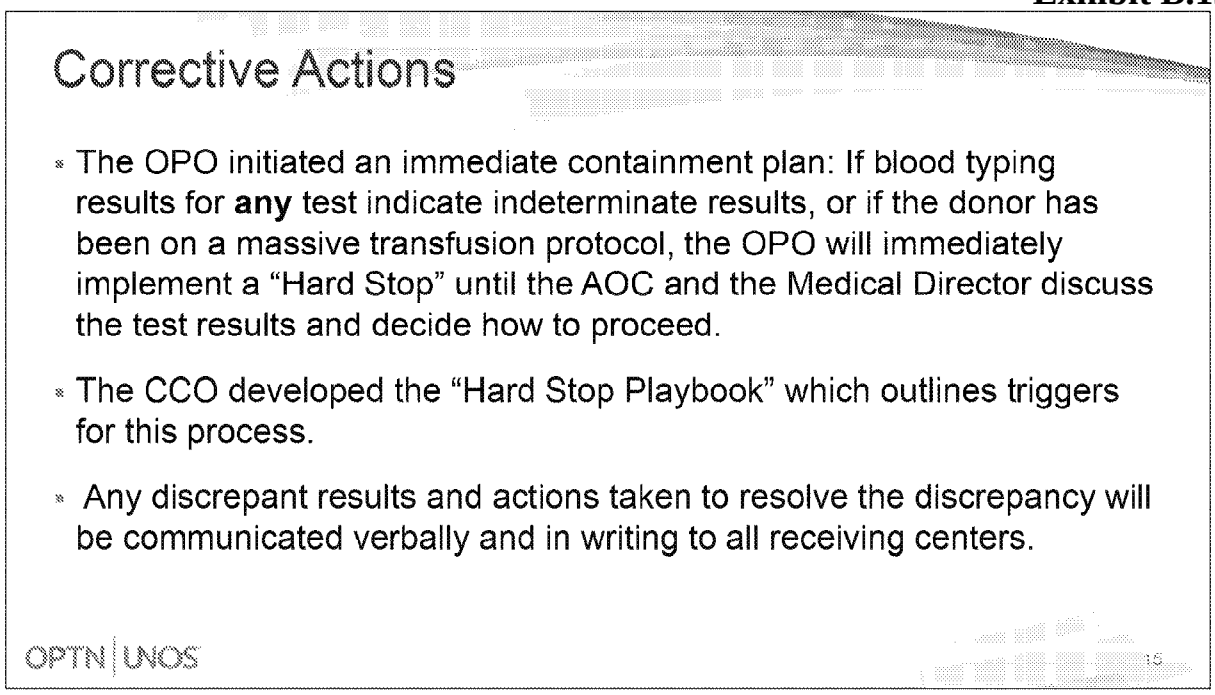
Hospital 46029N received the liver and transplanted it into an ABO O recipient. The recipient is doing well and is not expected to have an adverse course related to the incompatible ABO.

Hospital 35577N received the pancreas for an ABO O recipient. Using blood taken during procurement, Hospital 35577N re-ran donor ABO and found a mix of A and O blood types. Hospital 35577N called OPO 02412N and was informed of the massive transfusion the donor received, and that OPO 02412N had one indeterminate blood typing result. Hospital 35577N aborted the procedure and did not transplant the intended recipient. The pancreas was later discarded.

Hospital 03283N received the lungs, the left kidney, and the right kidney. The left kidney was transplanted into an ABO O recipient. The graft is functioning well and Hospital 03283N believes that the ABO incompatibility will not affect graft function. The right kidney was discarded after the ABO discrepancy was found.
The lungs were transplanted into an ABO O recipient who showed immediate signs of rejection and was put on ECMO. The lung patient died the next day.

Root Cause Analysis

- At the time of the event, the OPO did not have a clear process to address an indeterminate result besides drawing another sample or checking for an available sample.
- At the time of the event, the OPO did not have a clear process for when an indeterminate result should be escalated to the Medical Director.
- The OPO also noted that staff did not adequately recognize and respond to the "Indeterminate" result from the outside laboratory.



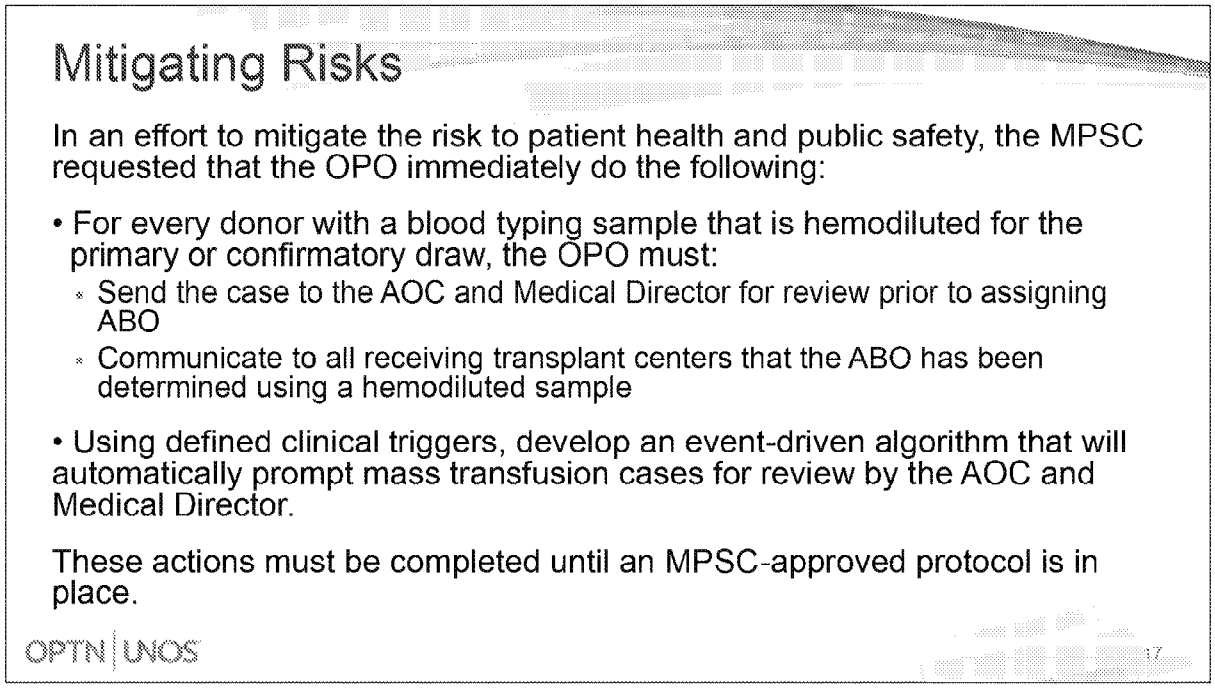
CCO: Chief Clinical Officer

Monitoring plans: OPO 02412N will monitor 100% of cases of indeterminate results and massive transfusion protocol for documentation of discussion between the AOC and Medical Director.

Leadership Call

- January 17th - MPSC Leadership reviewed the OPO's containment plan and response to the event. Leadership was concerned by:
  - Failure of OPO's staff and AOC to recognize the potential safety consequences of indeterminate blood typing issues
  - Use of broad terminology such as mass transfusion and indeterminate blood type instead of firm clinical and situational triggers when determining which donor cases go for AOC and Medical Director review
  - OPO did not accept responsibility for this event and look internally to assess what OPO staff could have done to prevent this event, regardless of the actions of the donor hospital

Offered the member an informal discussion to gather more information

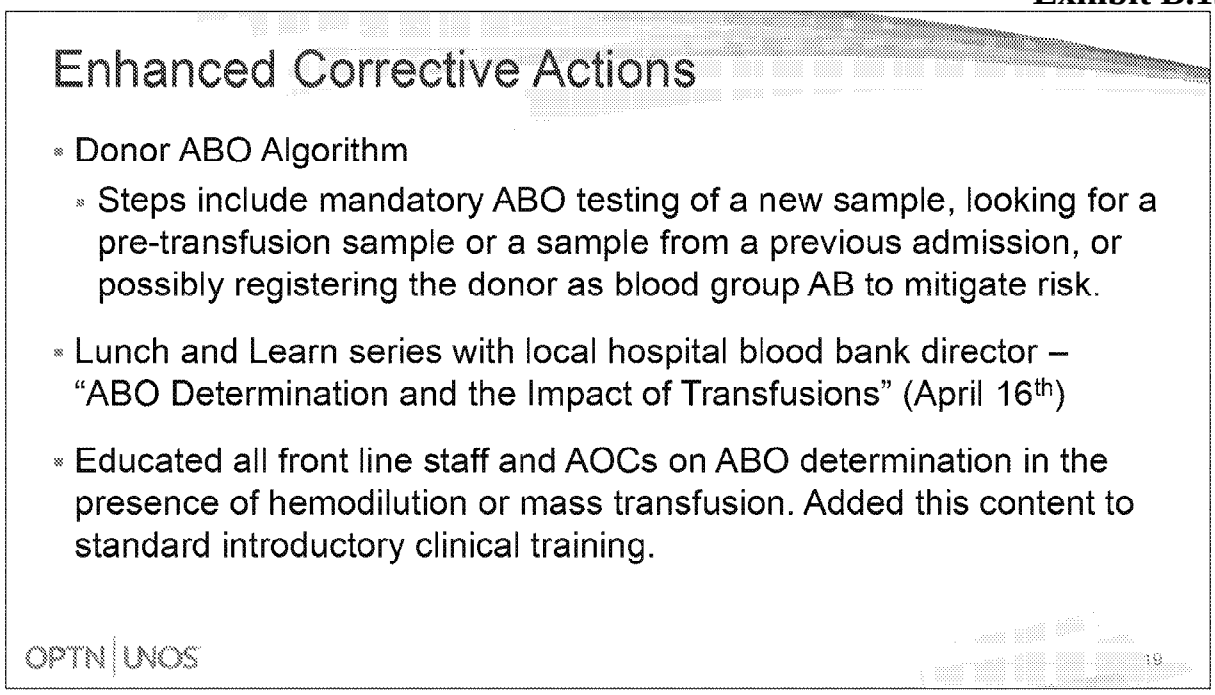


The MPSC has also requested that the OPO submit the following documentation:
• An updated RCA that includes a comprehensive internal assessment of actions the OPO could have taken to prevent this type of event.
• An updated corrective action plan that includes policy development and staff and leadership training regarding mass transfusions and ABO typing.

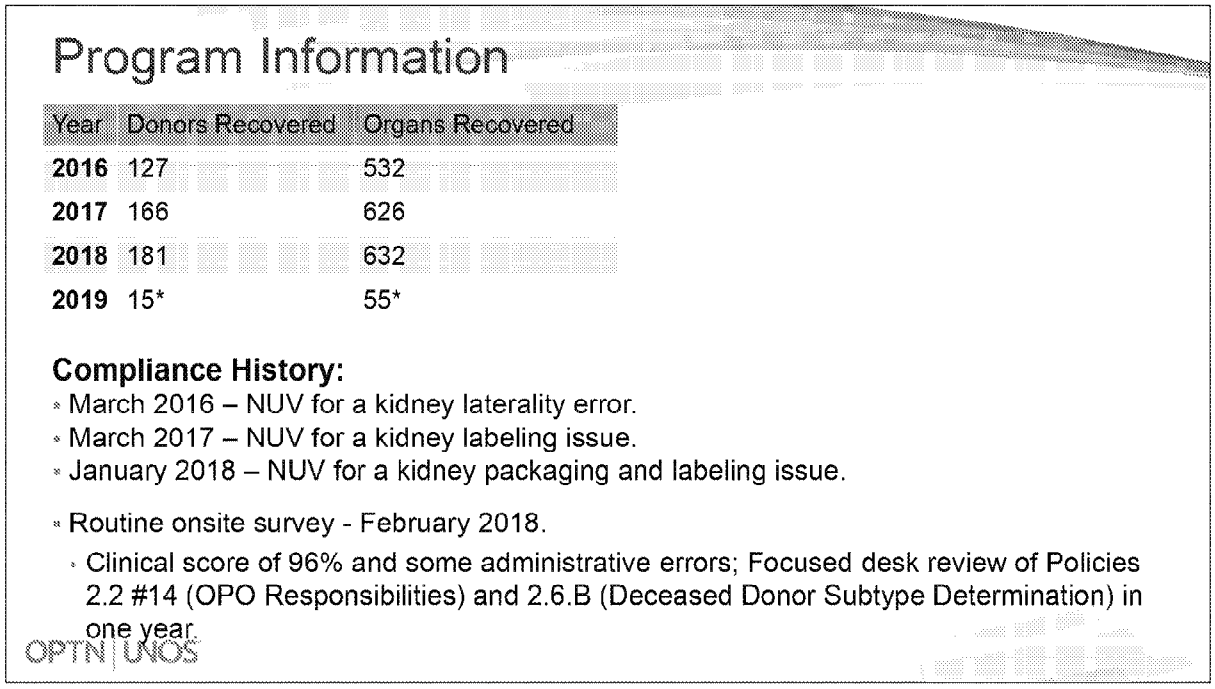
Also requested but not listed in the letter:
An description of the role and scope of responsibilities of the Medical Director at the OPO.

Informal Discussion

- January 28, 2019
- Presented a more robust RCA and CAP, identifying several internal actions that could be implemented to mitigate the risk of recurrence.
- Discussed their search for guidance material on ABO determination in the presence of hemodilution and massive transfusions.



The donor ABO algorithm is a process map for identifying & resolving ABO determination in hemodilution and massive transfusion protocols.

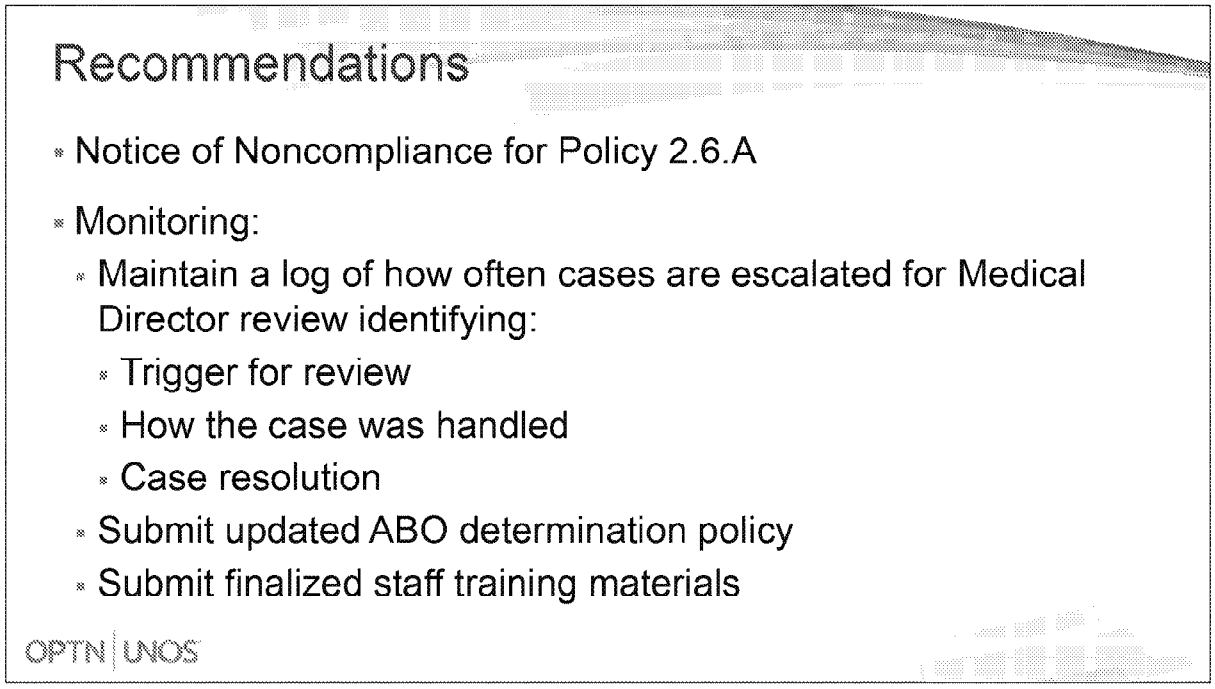


Data through 1/31/19.
For Policy 2.6.B, two donor records had ABO subtypes listed as A2, both source documents report subtype A1. All organs from both donors went into blood group A recipients.

For Policy 2.2 #14, one donor record was missing ABO, subtype, and infectious disease source documentation in DonorNet.

RCA (subtyping): OPO changed serology labs in late 2016 and failed to train staff on new ABO reporting format. Staff confused subtype reporting with Rh factor. Containment plan: Quality Dept. will audit every donor's ABO subtyping entry into DonorNet prior to the donor leaving for the OR for the next 30 days or the completion of the RCA and CAP.

Scheduled desk audit of 2.2.14 and 2.6.B is in September 2019.



Workgroup date – January 22

2.6.A Deceased Donor Blood Type Determination and Reporting

CAP Updates – 2/22/19

- Requiring that all blood samples for ABO testing be evaluated for hemodilution and qualified using the process for serology testing. A quality check of the process and results were submitted. (Att. 1)
- Completed a second, more formal case review of the event. (Att. 2)
- Finalized the ABO Determination and Results process maps. (Att. 3)
- Updated standard clinical training to include ABO Determination – Forward and Reverse Typing, discussing the impact of transfusions and hemodilution. Discussing this may be a "stand-alone" training for staff. PowerPoint submitted. (Att. 4)

OPTN | UNOS

CAP Updates – 2/22/19

- Updated policies (Att. 5)
- Monthly review of the Hard Stop process to ensure adherence to process, results of the first quality review were submitted. (Att. 6)

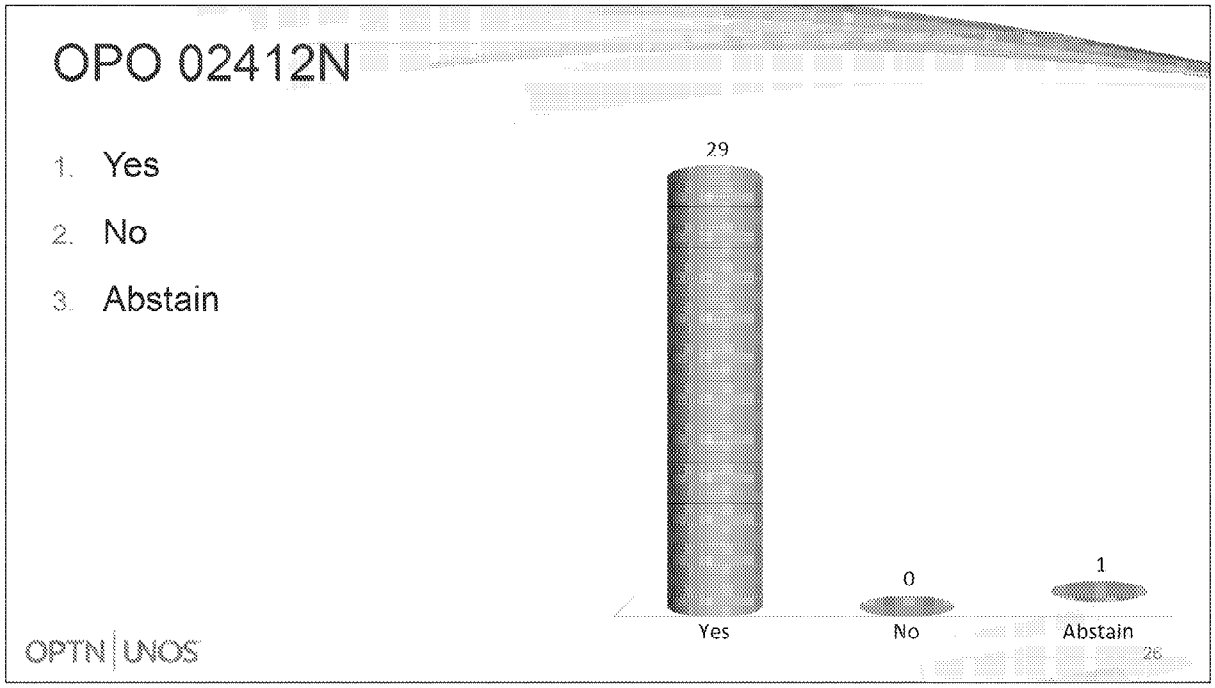
OPTN | UNOS

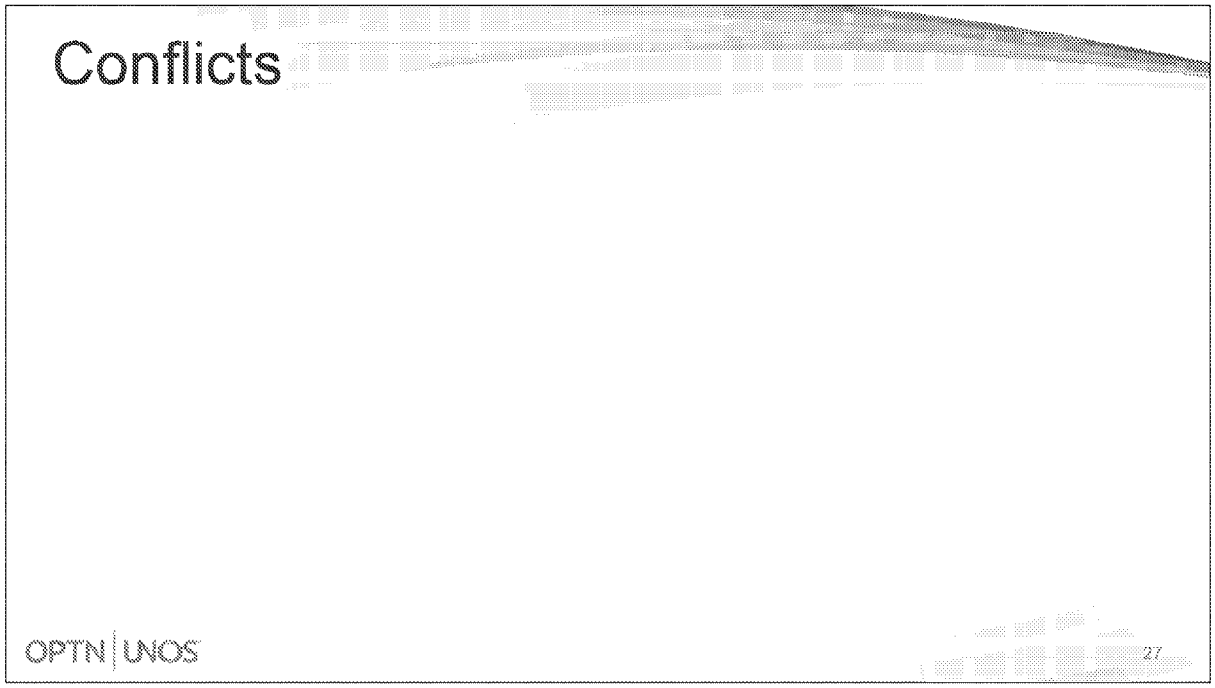
Items for Consideration

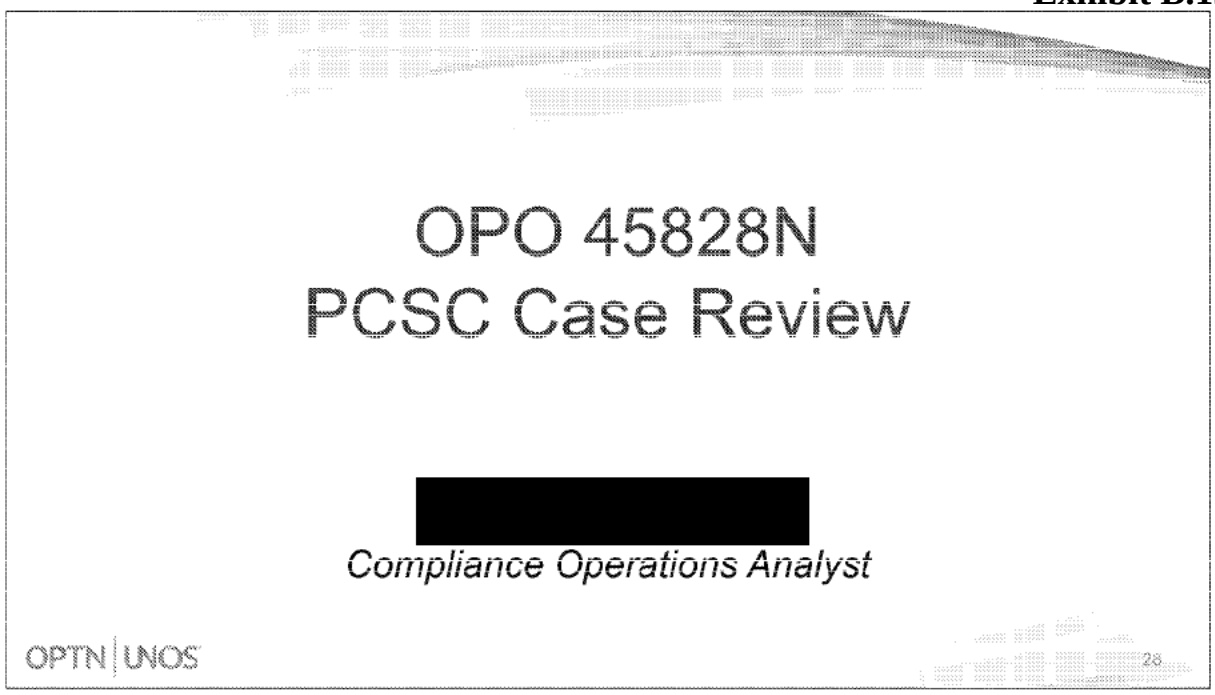
Does the MPSC approve the subcommittee's recommendations?

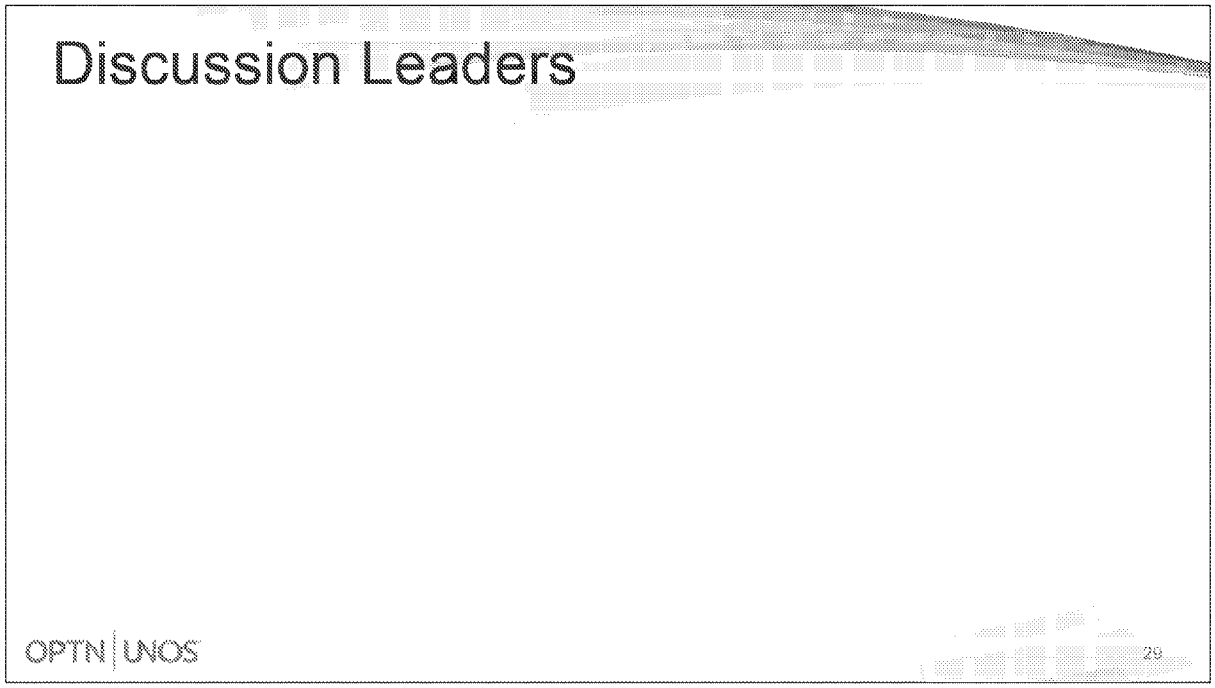
MPSC Resolution

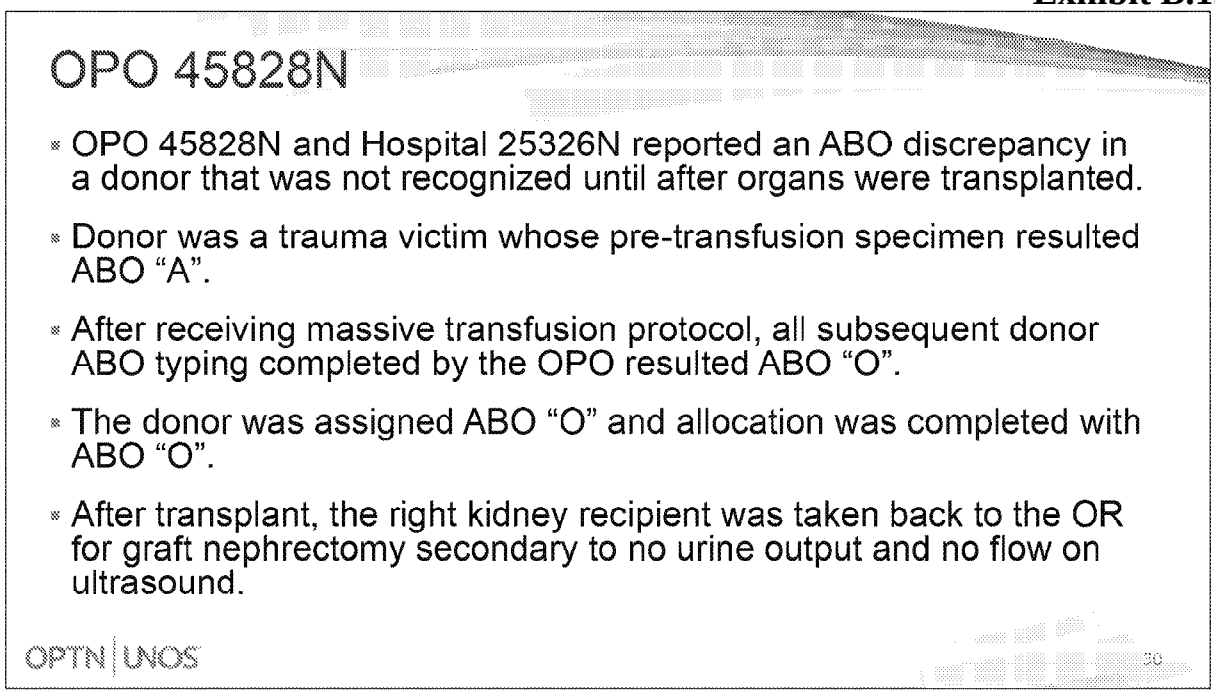
- Notice of Noncompliance for Policy 2.6.A
- Monitoring:
  - Maintain a log of how often cases are escalated for Medical Director review identifying:
    - Trigger for review
    - How the case was handled
    - Case resolution
    - Include in letter: in cases of unexpected graft failure, may consider looking at that case to see if it didn't meet these criteria but still had ABO issues


OPO 02412N
1. Yes
2. No
3. Abstain
29
0
1
Yes
No
Abstain
OPTN | UNOS
26


Conflicts
OPTN | UNOS
27


OPO 45828N
PCSC Case Review
[redacted]
Compliance Operations Analyst
OPTN | UNOS
28


Discussion Leaders
OPTN | UNOS
29



2.6 Deceased Donor Blood Type Determination and Reporting: "Host OPOs must develop and comply with a written protocol for blood type determination and reporting..."

OPO 45828N

- Liver transplant surgeon immediately notified. Liver recipient underwent plasmapheresis and continues to not show any signs of rejection.
- Left kidney in transit when the accepting center received notification of the potential ABO incompatibility issue. Center reviewed the details and elected to transplant the kidney into the intended recipient, as that patient was ABO "A."
- No other organs from this donor were allocated.

Corrective Actions

- Local transplant hospital blood bank Medical Director provided training on ABO typing processes, including ABO discrepancies, for OPO staff.
- Training was recorded for use in new employee training.
- OPO updated policy and procedures to include more specific guidance about what to do in the presence of discrepant results, most notably, to use the most restrictive ABO if the discrepancy is not resolved.
- Current clinical coordinators trained on ABO, HLA, and Archive Serum verification.
- ABO training for new employees will be updated to include the necessary steps to resolve primary blood base type discrepancies.

Volumes and History

Year	Donors	Organs Recovered
2016	70	244
2017	68	263
2018	68	226
2019	4*	19*

*As of February 14, 2019

MPSC history:

- 10/2016: NUV for rescinded liver offer and an expedited recovery where the OPO did not acquire all tissue-typing material or make mandatory share offers within the required time period.
- 6/2016: Board of Directors released OPO from Probation. (OPO placed on Probation in November 2014 for site survey issues, self-reported violations, and the results of a peer visit.)

Survey: Unannounced on-site survey as part of OPO's Probation monitoring. Clinical score 99%, few admin errors. MPSC 2/2016 closed with no action.

OPTN | UNOS

33

Reviewer Comments

Reviewer 1: I can agree to the Notice of Non-compliance with OPTN 2.6, but due to the nature of these case (including the loss of a kidney), I would recommend we look at this closer at this case and consider a review of Policy 2.6 to actually be more prescriptive in how these types of donors should be listed in DonorNet.

Reviewer 2: This major event should be discussed at the meeting as it has implications for safety across the system. I was not aware of the potential for mistyping to occur under these circumstances although in reading about "mixed field" it seems this is a real possibility in trauma cases where extensive blood is needed immediately (and therefore O is used). Frankly it is surprising this hasn't occurred before (or has it?) It may be there should be some additional policy development related to donors who type as O in these circumstances -major trauma, significant type O blood units, hemodiluted sample, prior discordant result.

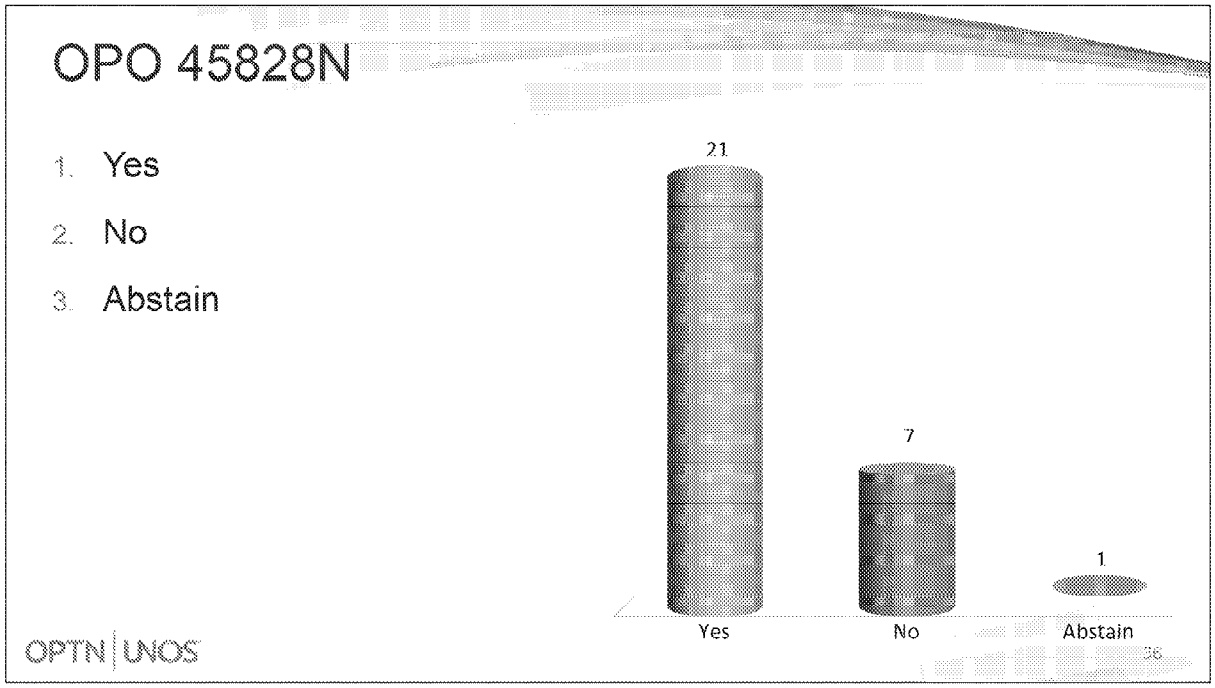
Reviewer 3: Agree with other reviewers that additional guidance should be provided on how to address these types of trauma patients for patient safety reasons and prevention of loss of transplantable organs. I do believe a notice of non-compliance is applicable, but would like to see the updates and guidance they have since provided to their staff. That was not provided with their submission.

Resolution

- Notice of Noncompliance for Policy 2.6.A
  - Submit monitoring of process and adherence to CAP

OPTN | UNOS

35


OPO 45828N
1. Yes
2. No
3. Abstain
21
7
1
Yes
No
Abstain
OPTN | UNOS
36

Relevant Policy

- **2.6.A Deceased Donor Blood Type Determination and Reporting**

  The host OPO must ensure that each deceased donor's blood type is determined by testing at least two donor blood samples prior to the match run. The host OPO must develop and comply with a written protocol to resolve conflicting primary blood type results.

  Deceased donor blood samples must:

  1. Be drawn on two separate occasions
  2. Have different collection times
  3. Be submitted as separate samples
  4. Have results indicating the same blood type

  The host OPO must document that blood type determination was conducted according to the OPO's protocol and the above requirements.

Case Comparison

	45828N	02412N
Event report date	• 9/28/2018	• 11/28/2018
Who reported?	• Donor OPO • Right Kidney Transplant Center	• Heart Transplant Center • Liver Transplant Center • Pancreas Transplant Center
Containment plan at time of reporting?	• Not applicable	• Yes - spoke with OPO day event reported and they had created a containment plan
Donor transfusion status	• Massive transfusion protocol. OPO reports 21 units within first 10 hours of admission.	• Massive transfusion protocol. OPO reports 26 units during attempt at life-saving surgery.

OPTN | UNOS

38

HRSA Notification? 045828N - NO, 02412N - YES

Case Comparison - Outcomes

	45828N	02412N
Left kidney	• Transplanted into ABO A recipient • Graft functioning	• Transplanted into ABO O recipient • Graft functioning
Right kidney	• Transplanted into ABO O recipient • Hyperacute rejection • Patient explanted and alive	• Discarded after ABO error found
Liver	• Transplanted into ABO O recipient • Patient plasmapheresed • No signs of rejection and alive	• Transplanted into an ABO O recipient • Graft functioning

OPTN | UNOS

39

Case Comparison - Outcomes

	45828N	02412N
Lungs	• Not recovered	• Transplanted into ABO O recipient • Hyperacute rejection • Recipient died the next day
Heart	• Not recovered	• Transplanted into ABO B recipient • Hyperacute rejection • Explanted, re-transplanted six days later with graft functioning
Pancreas	• Not recovered	• Allocated to an ABO O recipient • Receiving center found ABO error while performing confirmatory typing • Discarded

OPTN | UNOS

40

Case Comparison - ABO

Donor ABO	45828N	02412N
Typing #1	• 9/23/18, pre-transfusion • ABO: A • Listed on transfusion record, not posted or removed from donor attachments	• 11/24/18, post-transfusion • ABO: O • ABO: Forward O, Reverse A • Reverse typing not communicated to OPO
Typing #2	• 9/27/18, post-transfusion • ABO: O	• 11/25/18, post-transfusion • ABO: Indeterminate • ABO: Forward O, Reverse A • OPO aware of discrepancy
Typing #3	• 9/25/18, post-transfusion • ABO: O • Forward O, Reverse A	• 11/25/18, post-transfusion • ABO: O • ABO: Forward O, Reverse O
Typing #4	• 9/27/18, post-transfusion • ABO: O	• Not applicable

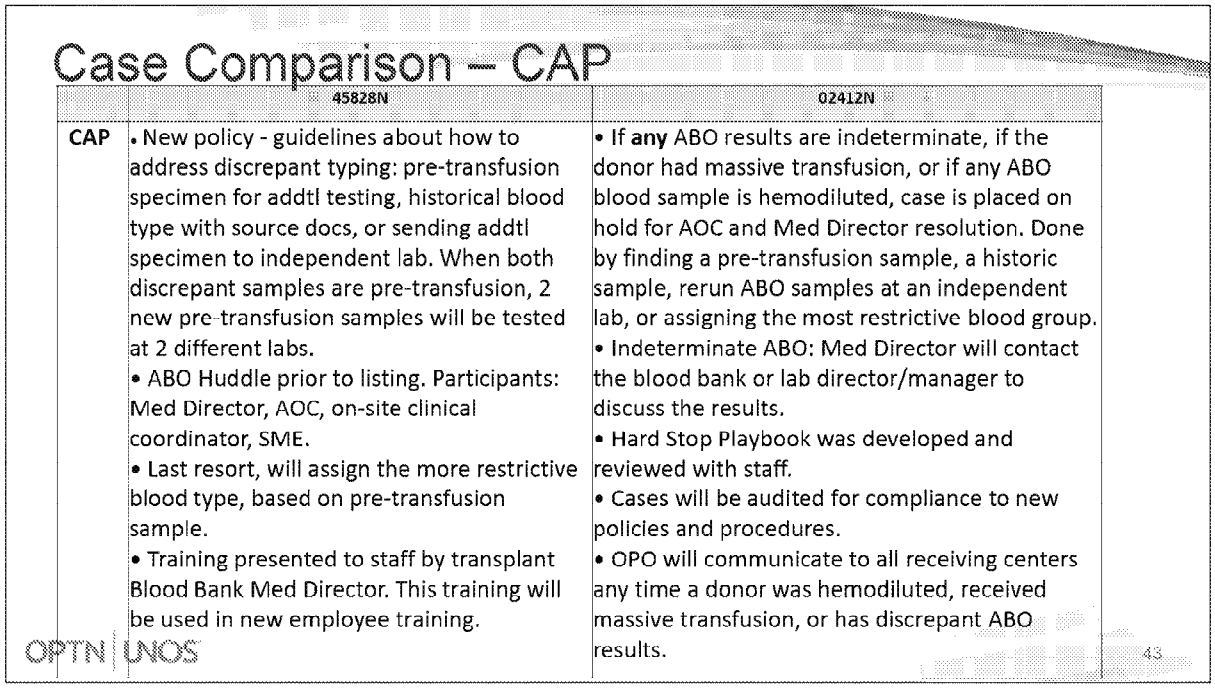
OPTN | UNOS

41

Case Comparison - Handling

	45828N	02412N
Why Donor Allocated as ABO O?	• Multiple results were obtained confirming ABO O, one of which was a non-hemodiluted sample	• OPO had two separate blood draws that indicated ABO O • Massive transfusion was not addressed as possible cause of ABO O result
Were centers informed of ABO discrepancies upon organ acceptance?	• No - ABO source documents were available in DonorNet • Recovery surgeon reviewed ABO source documents at time-out prior to recovery	• No - OPO did not consider discrepant as they had confirmatory testing.
Was ABO discussed with Medical Director?	• Yes	• No

OPTN | UNOS 42


Case Comparison – CAP
45828N
02412N
CAP
• New policy - guidelines about how to address discrepant typing: pre-transfusion specimen for addtl testing, historical blood type with source docs, or sending addtl specimen to independent lab. When both discrepant samples are pre-transfusion, 2 new pre-transfusion samples will be tested at 2 different labs.
• ABO Huddle prior to listing. Participants: Med Director, AOC, on-site clinical coordinator, SME.
• Last resort, will assign the more restrictive blood type, based on pre-transfusion sample.
• Training presented to staff by transplant Blood Bank Med Director. This training will be used in new employee training.
• If **any** ABO results are indeterminate, if the donor had massive transfusion, or if any ABO blood sample is hemodiluted, case is placed on hold for AOC and Med Director resolution. Done by finding a pre-transfusion sample, a historic sample, rerun ABO samples at an independent lab, or assigning the most restrictive blood group.
• Indeterminate ABO: Med Director will contact the blood bank or lab director/manager to discuss the results.
• Hard Stop Playbook was developed and reviewed with staff.
• Cases will be audited for compliance to new policies and procedures.
• OPO will communicate to all receiving centers any time a donor was hemodiluted, received massive transfusion, or has discrepant ABO results.
OPTN UNOS
43

From: [redacted]
To: [redacted]
Cc: [redacted]
Subject: FW: MPSC: Informal Discussion Offer
Date: Tuesday, January 22, 2019 1:23:42 PM
Attachments: [redacted] SCOP Informal Discussion Offer .pdf
Importance: High

Dear [redacted]

Thank you for your call today. Here is a summary of the items we discussed during our conversation.

- You asked if SCOP should present a slide deck for the informal discussion. I replied that you could submit any information that you want the MPSC to review in any format, but that it can be helpful for reviewers to refer back to information presented on a slide for reference.
- You discussed SCOP's search for additional information after this event (from blood banks and other sources). You voiced concern that this type of event may be a larger issue in the community. I stated that your presentation to the MPSC should primarily address the concerns stated in the Informal Discussion Offer letter and focus on the mitigating and corrective actions SCOP can take on its own to prevent recurrence of this event. Please save any larger community issues for the last minute(s) of the presentation or present this information separately prior to the discussion. If the MPSC feels that this issue is a larger community issue, they will address it as an educational referral to UNOS staff for further consideration.
- Feel free to ask MPSC reviewers for suggestions; they are your peers and they are available to you as a resource during the question and answer portion of the informal discussion.
- I stated that I believe with 90% certainty that the informal discussion will be on held on Monday, January 28th in the afternoon. Please arrange for OPO staff to be available for the discussion if possible. There will be more instructions in the scheduling letter coming tomorrow.

Feel free to reach out if you have any additional questions or concerns.

Kind regards,

[redacted]
Compliance Operations Analyst
Member Quality

UNOS UNITED NETWORK FOR ORGAN SHARING

Matching organs. Saving lives.

[redacted]

www.unos.org

From: [redacted]@unos.org>
Sent: Tuesday, January 22, 2019 11:38 AM
To: [redacted]@sharinghopesc.org>
Cc: [redacted]unos.org>
Subject: MPSC: Informal Discussion Offer
Importance: High

[redacted]

This email is your notice that I have received your written acceptance of the MPSC's Informal Discussion offer. I have attached the Informal Discussion Offer letter you requested, sent via regular email so you can open it while traveling. There is nothing else I need from you today. The information requested from the MPSC in the letter can be presented during your portion of the informal discussion or sent earlier for MPSC review if you would like to use your presentation time for other material.

Sometime tomorrow, I will be sending you a scheduling letter and a document providing a high-level overview of what to expect when preparing for an informal discussion. Let me know if you have any questions.

Kind regards,

[redacted]
Compliance Operations Analyst
Member Quality

UNOS UNITED NETWORK FOR ORGAN SHARING

Matching organs. Saving lives.

[redacted]

www.unos.org

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 ID [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
	No	02/8/19 13:30 VRL	A(1) neg.	NA	02/8/19 13:40 VRL A(1) neg.	NA
	No	02/8/19 23:35 VRL	O pos.	NA	02/8/19 23:30 VRL O pos.	NA
	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.
	No	02/10/19 9:50 Hospital	O pos.	NA	02/10/19 12:10 VRL	NA

					O pos.	
[redacted]	NA	02/12/19 19:07 Hospital	O pos.	NA	02/14/19 21:50 VRL O pos.	NA
	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 AFKY198[redacted]

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 [redacted] policy).

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

[redacted] 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]
Dr.[redacted] (Pronouncing MD)
Dr.[redacted] abdominal transplant)
Dr.[redacted] ung)
Dr.[redacted] 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 [redacted] 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 [redacted] 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-
Kidneys-
Pancreas-
Lungs-
Heart-

TISSUE PLACEMENT Tissues and Corneas recovered

POST ORGAN RECOVERY DISCOVERY

CAT was notified by [redacted] 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 [redacted]

[redacted] 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 [redacted] also resulted as A.

ORGAN OUTCOME

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

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

Heart- [redacted] 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 [redacted] 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?

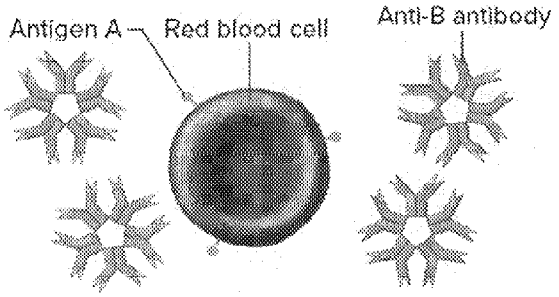
ABO TYPING

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

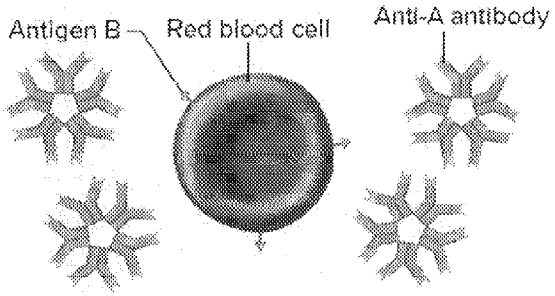
·Forward Typing- this test is used to detect the presence or absence of A and/or B antigens on ***red blood cells***. ABO group is *determined*.

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

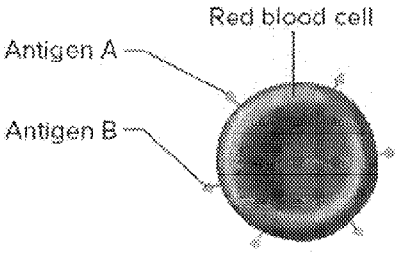
·D typing not relevant to transplantation.



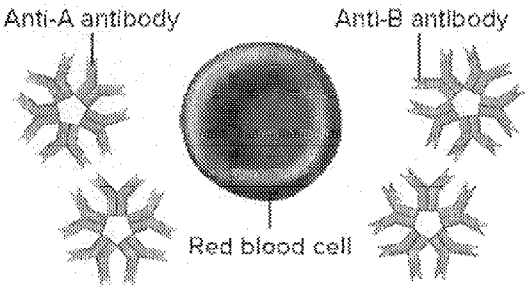
Type A blood



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".

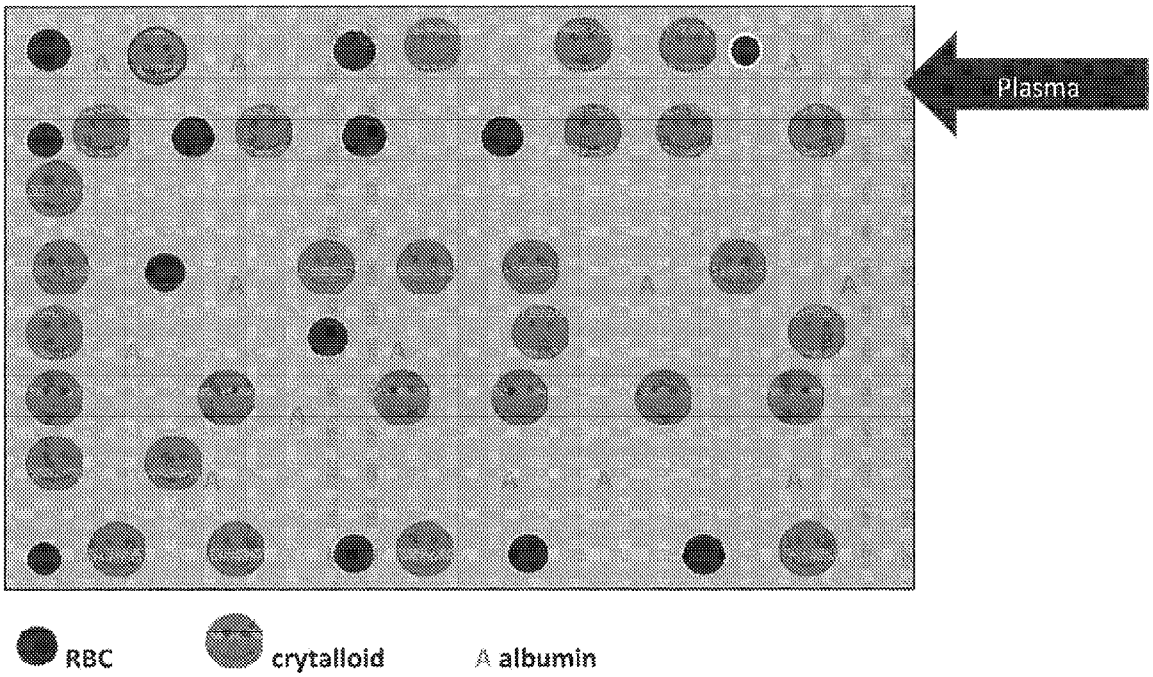
There are 2 ways to become hemodiluted:

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.

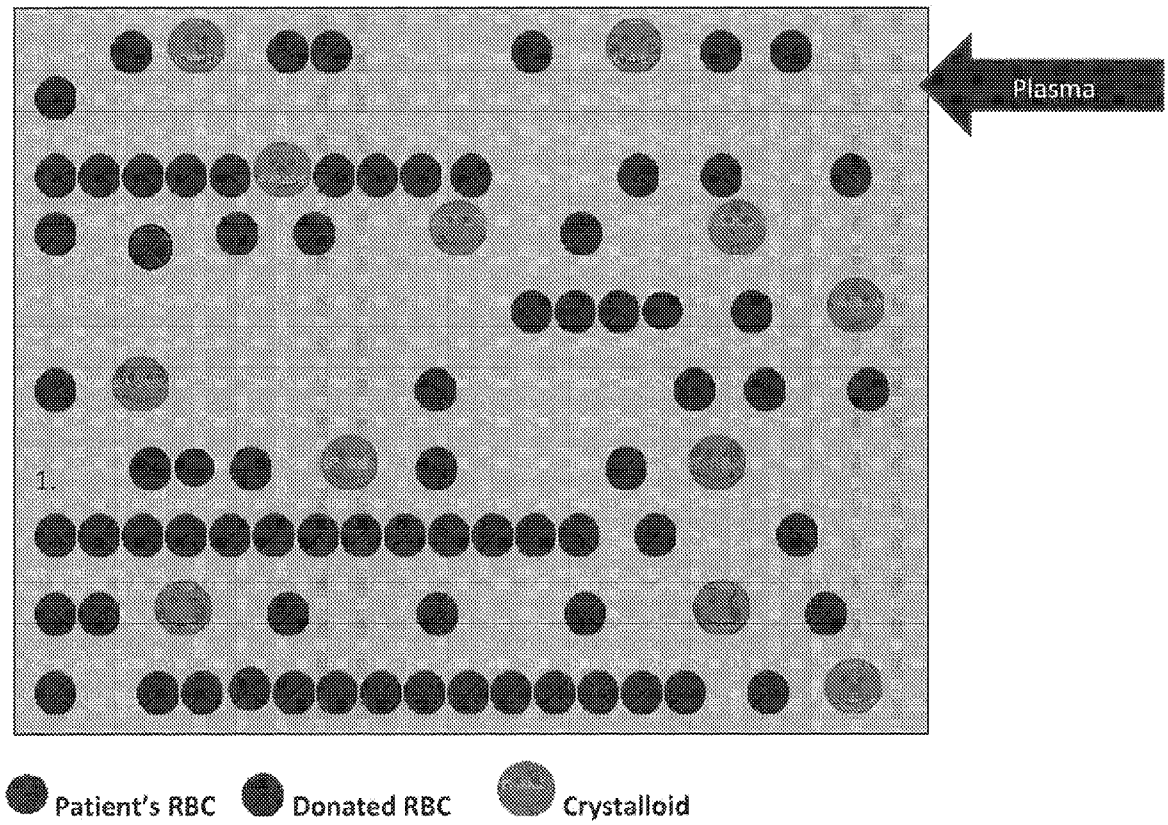
2. Massive blood product transfusion. The ratio of donated blood cells and/or plasma is greater than the patient's own blood volume and circulating blood cells.

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]

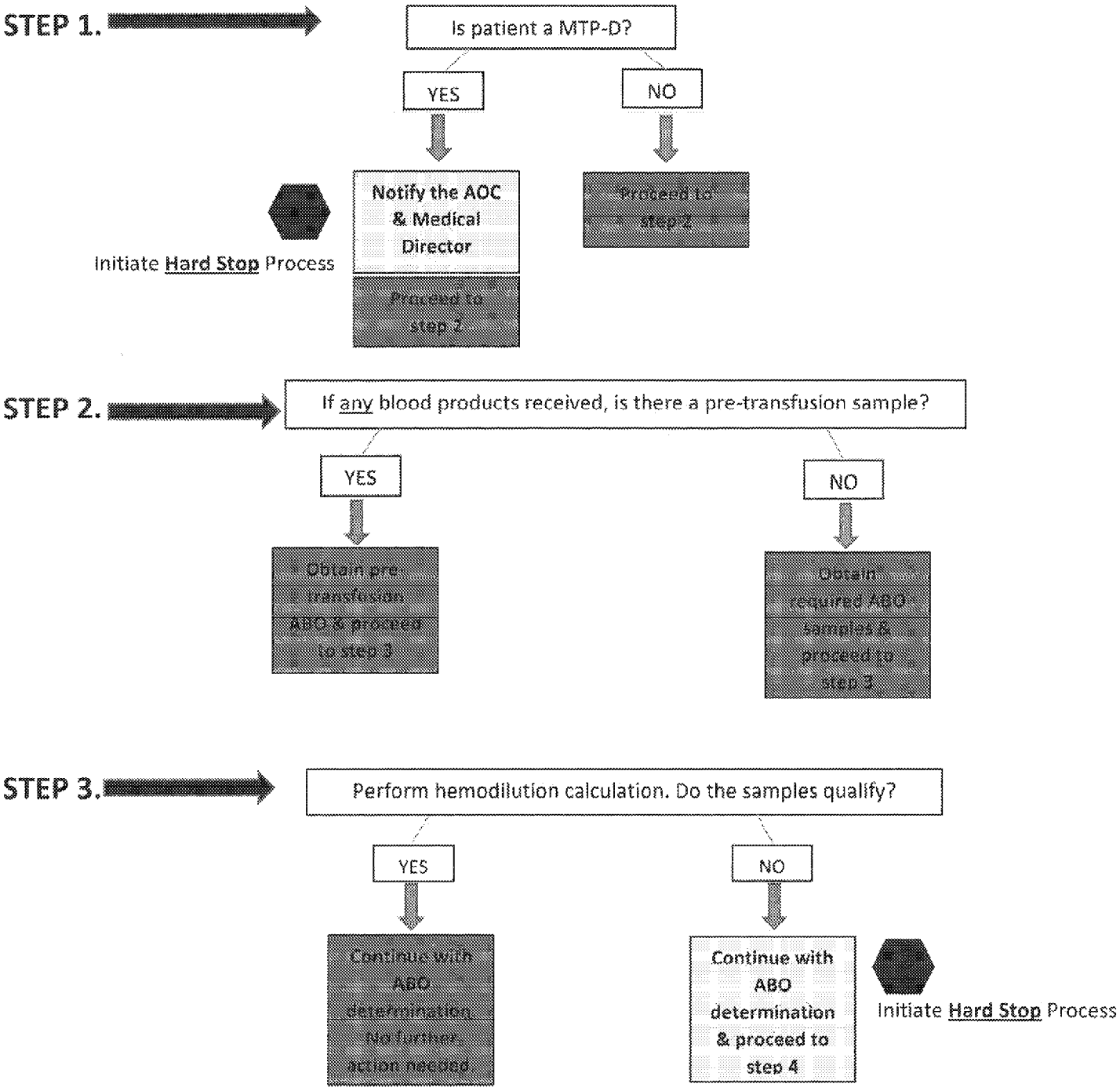
ABO Results Process Map

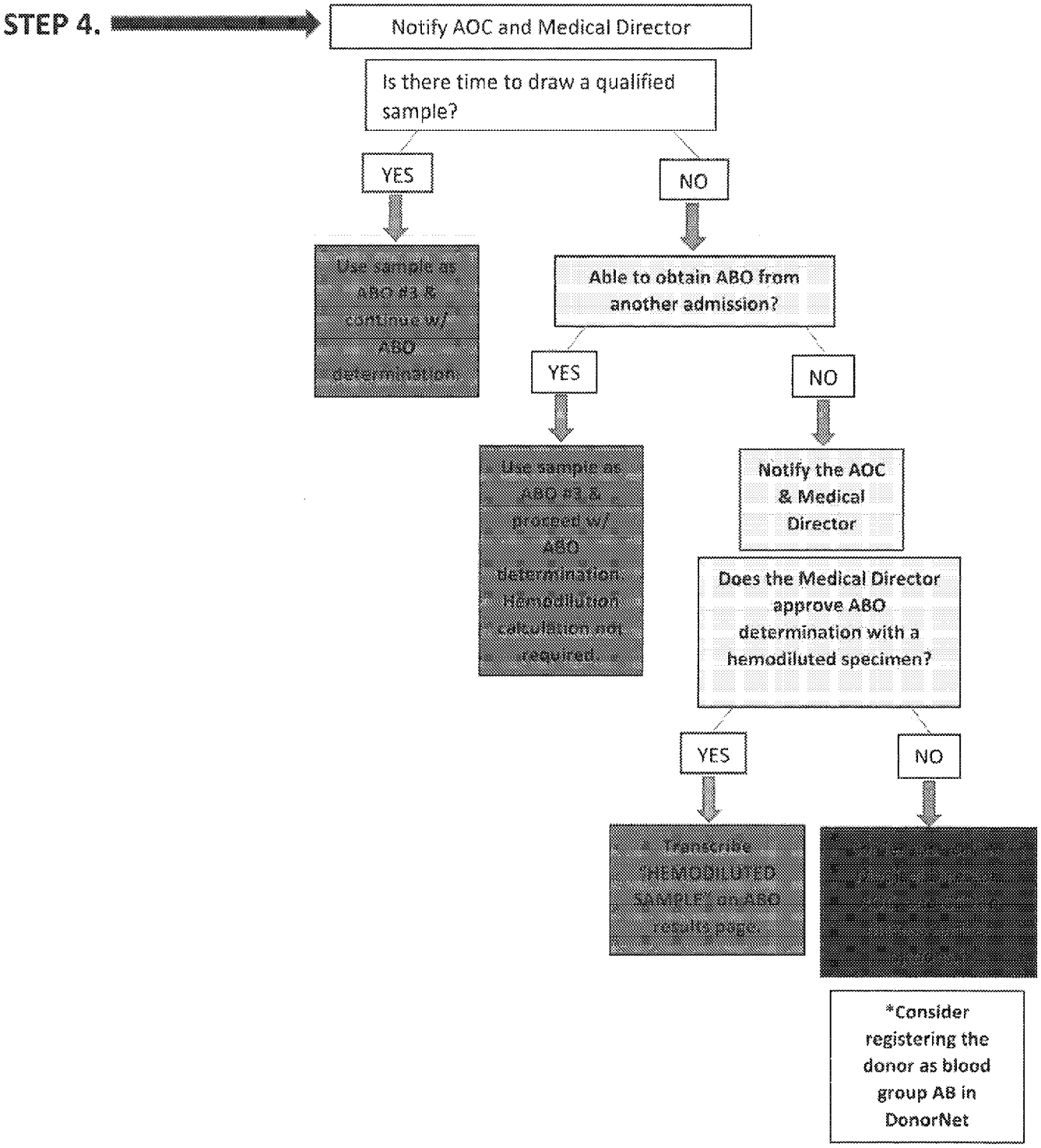
1. **Any ABO Results Indeterminate**
   No – [Proceed with Donation]
   Yes – [Notify AOC and Medical Director] [OPO MUST re-run another ABO x 2]

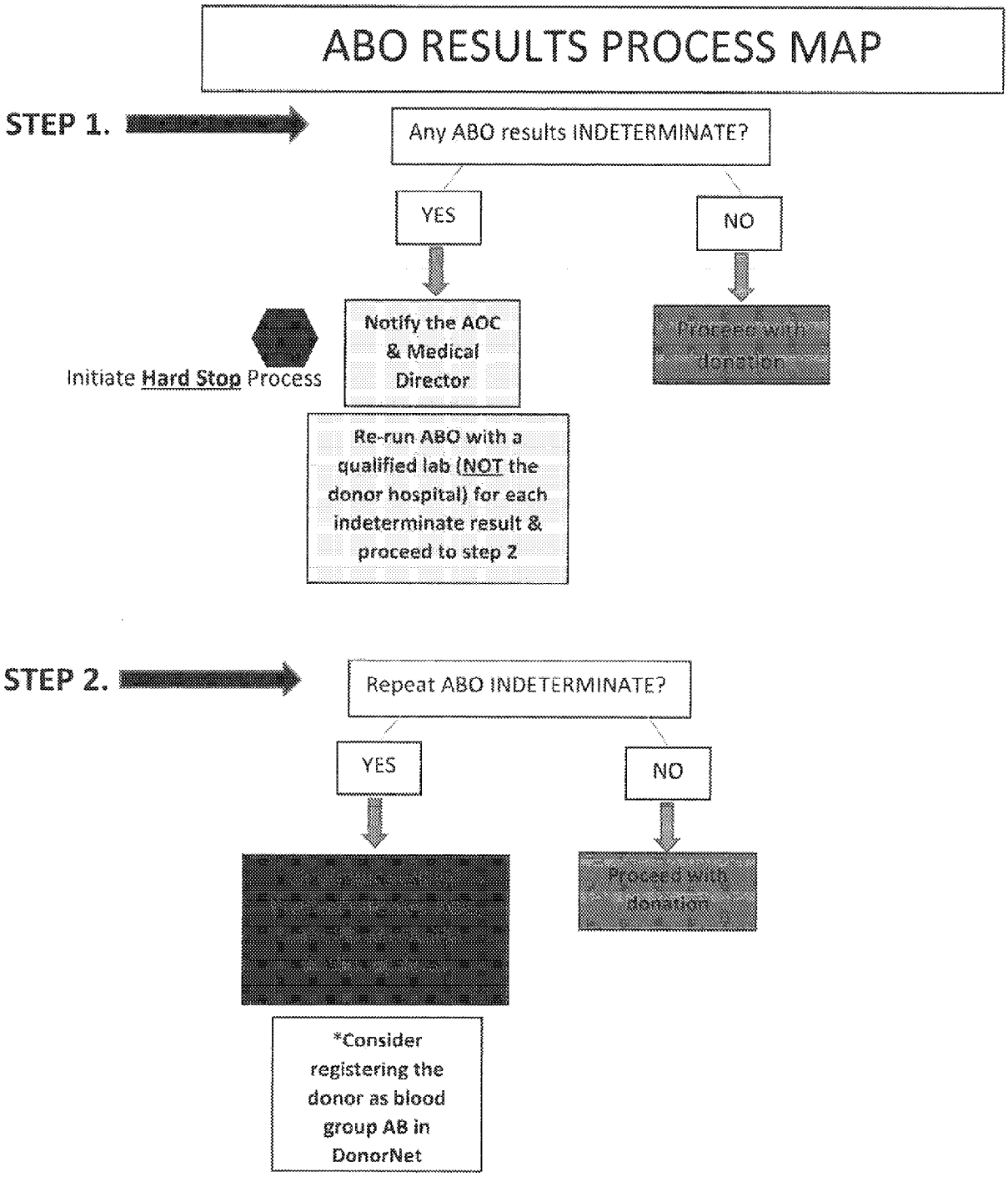
2. **Repeat ABO result is Indeterminate**
   No – [Proceed with Donation]
   Yes – [Notify AOC and Medical Director]

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.

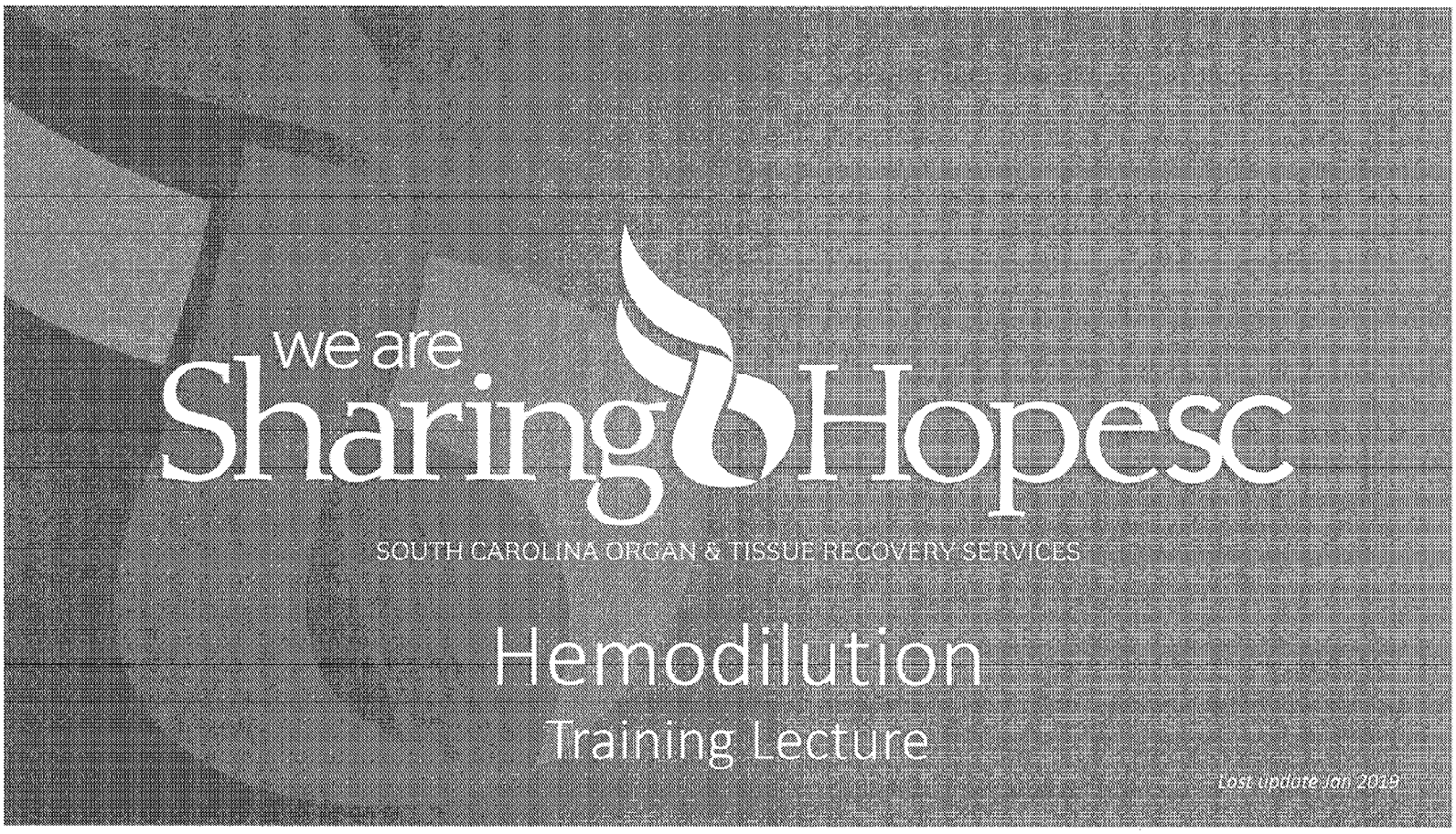
This form has been reviewed by the representative of the accepting transplant center. ALL signatures must be received from the accepting transplant center before the OR time can be set for organ recovery.

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 17 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 17 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 [redacted]	Donor ID	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.			

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[redacted]

CONFIDENTIAL MEDICAL PEER REVIEW

March 13, 2019

VIA SECURE EMAIL

[redacted]
CEO/President
OPTN/UNOS Representative
We Are Sharing Hope SC
[redacted]

[redacted]
Medical Director, Organ Division
We Are Sharing Hope SC
[redacted]

Dear [redacted]

As you know, Membership and Professional Standards Committee (MPSC) leadership, including the Vice Chair, Chair of the Performance Analysis and Improvement Subcommittee (PAIS), and Chair of the Policy Compliance Subcommittee (PCSC), along with the OPTN President reviewed We are Sharing Hope's (SCOP) root cause analysis, containment plan and corrective actions regarding donor [redacted]'s ABO determination that led to incompatible transplants. After this review, the leadership group requested additional specific information and requested that the program participate in an informal discussion to discuss this case.

SCOP participated in an informal discussion on January 28, 2019 with an MPSC subcommittee. The MPSC met on February 27, 2019, and reviewed submitted documentation and the subcommittee's recommendations.

Based on its review, the MPSC approved the following:

> RESOLVED, that the Membership and Professional Standards Committee issues a Notice of Noncompliance to We are Sharing Hope for violation of Policy 2.6.A (Deceased Donor Blood Type Determination).

The Committee voted 29 For; 0 Against; and 1 Abstention.

[redacted]

[redacted]
We Are Sharing Hope SC
March 13, 2019
Page 2

CONFIDENTIAL MEDICAL PEER REVIEW

The MPSC also requests that SCOP submit the following documentation for MPSC review:

- A log of all cases escalated for Medical Director review identifying:
  - The trigger that escalates the case for review
  - Steps taken by the AOC and Medical Director to resolve the case
  - The case resolution

The MPSC also suggests that SCOP consider looking at additional cases of unexpected graft failure. SCOP may want to look at those cases, even if they did not meet their criteria for review, to determine whether they may also have blood type determination issues. Please submit the requested documentation to [redacted] Compliance Operations Analyst, no later than **May 23, 2019**.

Pursuant to the above resolution, the MPSC hereby issues this Notice of Noncompliance to SCOP.

Please note, a Notice of Noncompliance is included in Appendix L of the Bylaws, which is accessible at http://optn.transplant.hrsa.gov. A Notice of Noncompliance is not an adverse action under the Bylaws but is meant to inform the member of the need to ensure continuing compliance with policies monitored by UNOS. A Notice of Noncompliance does not need approval from the Board of Directors and is not made public. UNOS will include the letter in your member compliance history, and it may be considered by the MPSC should future compliance issues arise.

Please be aware that this correspondence and all related documents and information are protected by applicable peer review statutes. Members must keep all information provided in the medical peer review processes and settings confidential. Therefore, all inquiries, deliberations, recommendations, and actions of the MPSC, Board of Directors, other committees, and Organ Review Boards must be kept confidential by members during the review process and after the matter is closed. The Board of Directors may make public certain final adverse actions as outlined in the Bylaws.

If you have any questions or concerns, or need any additional information regarding this resolution, please contact [redacted]

Sincerely,

[redacted]
Vice Chair, OPTN/UNOS Membership and Professional Standards Committee

[redacted]

[redacted]

From: [redacted]
Sent: Wednesday, November 28, 2018 1:26 PM
To: [redacted]
Cc: [redacted]
Subject: [send secure] Recent SCMU transplants

This message was sent securely by MUSC

[redacted] **Kidneys and Lungs from SCOP Grand Strand *PHS Increased Risk Hemodilution *XClamp 11/27 @ 2130***

SCMU Kidneys – Timeline of events

SCMU on-call coordinator: Received call from MD [redacted] (SCMU abdominal transplant surgeon) 11/28 @ 0200 requesting ABORH run on blood sample from donor due to potential for blood group incompatibility. States information received from Sharing Hope who indicated that the Wisconsin team who received the solitary pancreas detected the donor blood group to be A. MD [redacted] inquired about patient [redacted] that was in the OR with MD [redacted] and MD [redacted] states he spoke to him and he is aware. Info relayed to [redacted] in HLA @ 0205. Blood bank director [redacted] also paged to MD [redacted] phone @ 0235. Called HLA back @ 0240 to check on the status and [redacted] stated that [redacted] went to the blood bank to explain the situation. He also stated that the SCMU HLA lab director was involved and they would let me know the outcome. Spoke with MD [redacted] @ 0248 and he confirms that he has spoken with the head of blood bank & he believes that ABO will be completed. Received call from MD [redacted] @ 0400 that ABORH typing came back as A and we will not be completing the second kidney transplant. All cancellations made, patient sent home. Sharing Hope, [redacted] notified to come pick up kidney. Per [redacted] Charge RN in OR the kidney is still on the pump, info relayed to Sharing Hope & kidney will be discarded.

Currently the kidney recipient is doing well –transplant date 11/28/2018 at 12:34 am (start of anastomosis) the kidney did perfuse in the OR and made urine. Patients creatinine has decreased from 7.6 to 5. We performed anti-A antibody testing and results indicate a 1:32 titer and planning for plasmapheresis.

SCMU Lungs – Timeline of events

Post-transplant the lung transplant surgeon spoke to the family re primary graft dysfunction as the patient required VA ECMO. At 0201 the lung transplant pulmonologist was notified by Sharing Hope of concern that donor ABO not accurate at 0346 the lung transplant pulmonologist received confirmation from the SCMU abdominal that MUSC typing of donor blood confirmed ABO A. 0430- the transplant pulmonology medical director arrived at MUSC and confirmed that the other transplant pulmonologist had already spoken to lung recipient's family.

Currently the lung transplant recipient (transplant date 11/27/18 anastomosis time 09:30) and has expired.

[redacted]
Director of Regulatory Affairs/Accreditation
[redacted]
Medical University of South Carolina
Transplant ICCE
[redacted]

This message was secured by **MUSC**.

[redacted]

From: [redacted]
Sent: Wednesday, November 28, 2018 1:46 PM
To: [redacted]
Cc: [redacted]
Subject: [redacted] 24-Hour Reportable Event - ABO Incompatible Transplant

HRSA Colleagues:

On November 28, 2018, the Member Quality Department received a report of four ABO incompatible transplants involving organs from a single donor allocated by OPO 02412N. Per Wakefield Criteria #6 (any issue that may pose a serious threat to patient safety) we are reporting this event to you. A summary is provided below of what we know about this event as of this moment:

Case Facts:

Donor ID#	[redacted]
Organs Transplanted	Bilateral Lung, Heart, Liver, Left Kidney
Organs Allocated but Not Transplanted	Pancreas, Right Kidney
Date of Donor Hospital Admission	11/24/18
Date Declared Brain Dead	11/25/18
Date of Organ Procurement	11/27/18
Transplant Dates	11/27/18 and 11/28/18
Date OPO Alerted	11/28/18
Date UNOS Alerted	11/28/18
Donor ABO Used in Allocation	O
Donor Correct ABO	A1

Available Case Information:
OPO 02412N managed a donor who received multiple units of blood products as part of a massive transfusion protocol. The first ABO typing performed was indeterminate, but the second and third typings indicated an ABO of O. Organs were allocated as O. The heart center transplanted the heart into an ABO B recipient; upon release of cross clamp surgeons saw immediate signs of rejection and the heart recipient was placed on ECMO. The left kidney recipient, ABO O, was transplanted and is "not doing well." The lung transplant recipient, ABO O, was transplanted, had acute rejection, was put on ECMO, and died. The liver recipient, ABO O, shows no signs of rejection and the surgical team feels optimistic that they can manage the transplant. It appears that the pancreas center and right kidney center did not proceed with transplant due to being informed of the ABO issue or via finding the ABO of A1 independently.

Donor Analysis:
The donor was a 24-year-old female who died from a motor vehicle accident. The donor was identified as PHS Increased Risk due to hemodilution. The initial indeterminate ABO was not mentioned in DonorNet.

I will provide any additional significant updates as they are identified.

Please let me know if you have any questions or concerns.

[redacted]
Safety Analyst

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[redacted]

[redacted]

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SFC OPTN Hearing Exhibit B.19

[redacted]

Choose an application

(/PatientSafety/Default.aspx?CTXT=tv7nhlZPMWyvTBFUbclmcyoQ2B1vllZK56nIT9LacJ3Vl%2F4FAKtrHQ%3D%3D)

Help

Improving Patient Safety

Safety Situation [redacted]

The goal of the Improving Patient Safety system is to collect information about safety related incidents occurring system-wide, in order to increase organ utilization and decrease the morbidity and mortality of transplant patients.

What is a Safety Situation?
A situation or activity that affected or could have affected patient safety.

What to report:

- Any patient safety situation
- Any other situation that causes a safety concern from a transplantation, donation, and/or quality perspective.

Please report such situations in a timely manner.

Below you will find the most current information for situation [redacted]. You can complete the following tasks on this page:

- Access a printer-friendly version of this safety situation
- Add resolution information

Situation Information

Reporting Institution: * **TNVU-Vanderbilt Univ Med Ctr-Transplant Hospital(Member)**

Type of Safety Event (Choose all categories and subcategories that are applicable): *

- [ ] Communication
- [x] Data Entry
  - [x] DonorNet
    - [ ] Donor ID
    - [ ] Demographics (e.g., height, weight, age, ethnicity)
    - [x] ABO
    - [ ] ABO Subtyping
    - [ ] HLA
    - [ ] Labs (e.g., creatinine, INR)
    - [ ] Infectious disease test result(s)
    - [ ] Increased risk (or high risk) status of donor
    - [ ] Other (please describe in the description field below)
  - [ ] Waitlist
  - [ ] Other (please describe in the description field below)
- [ ] Transportation
- [ ] Packaging/Shipping
- [ ] Labeling
- [ ] Recovery Procedure/Process
- [ ] Transplant Procedure/Process
- [ ] Testing
- [x] Organ Allocation/Placement
  - [ ] Offer rescinded
  - [ ] Offer not made to secondary contact
  - [ ] Out of sequence allocation
  - [ ] Inaccurate patient priority or status
  - [ ] Recipient not on match run
  - [ ] Inaccurate donor data caused match to run incorrectly
  - [ ] Match not rerun once serology found to be positive
  - [x] Other (please describe in the description field below)
- [ ] Other (please describe in description field below)

The Issue reported involves the following (choose all categories that are applicable): *

- [x] **Recipient/Candidate**

SFC OPTN Hearing Exhibit B.19

Waitlist ID: **No Waitlist ID:** ☑

SSN: ✳ [redacted]

☑ **Donor Organ/Extra Vessels**

Donor ID associated with the event: ✳ [redacted]

Did this event involve the entire donor or were only specific organs involved? ✳ Entire Donor

Organ Type

- ☐ Right Kidney
- ☐ Left Kidney
- ☐ Double/En-bloc Kidney
- ☐ Pancreas
- ☐ Pancreas Segment 1
- ☐ Pancreas Segment 2
- ☐ Liver
- ☐ Liver Segment 1
- ☐ Liver Segment 2
- ☐ Intestine
- ☐ Intestine Segment 1
- ☐ Intestine Segment 2
- ☐ Heart
- ☐ Right Lung
- ☐ Left Lung
- ☐ Double/En-bloc Lung
- ☐ Extra Vessel(s)

Did this safety situation cause or contribute to:

The non-recovery of organ(s)? ✳ Unknown

The discard of any organ(s)? ✳ Unknown

A delay (prolonged ischemic time) for any organ(s) transplanted? ✳ Unknown

☐ **Other (please describe in the description field below)**

Date Event Occurred: ✳ 11/27/2018

Detailed Description of the Event: ✳ VUMC accepted donor organ AFKY198 for our recipient. All OPO and DonorNet data stated this donor was ABO O, which was compatible with our recipient. After transplantation occurred, we were notified that the donor's ABO was actually A, making the donor incompatible with our recipient. We are now following our own ABO incompatible protocol in an attempt to manage this recipient and organ.

Has a root cause analysis (RCA) been completed? ✳ ○ **Yes** ◉ **No** ○ **In Progress**

Please specify additional details regarding the RCA: We were just made aware of this event this morning; no RCA has been able to be completed yet.

Please upload any relevant attachments:

Contact Information

Who at your institution should UNOS contact about this case?

First Name: ✳ [redacted] **Last Name:** ✳ [redacted]

Phone contact (Enter at least one): ✳

Office: [redacted] **ext.** **Pager/beeper:** **ext.**

Mobile: **ext.** **Other:** **ext.**

Email: ✳ [redacted]@vumc.org

Other contact info:

UNOS Only

Reported by: Jenna Lawson

Initial UNOS Action

Date: ✳ 11/28/2018 **Staff member:** [redacted]

Status: ✳ In process ▼ **Urgency:** ✳ Medium ▼

Category: ✳ Critical ▼

Potential policy violation: ○ **YES** ○ **NO**

Committee notification? ○ **YES** ○ **NO**

Type of Safety Event (Choose all categories and subcategories that are applicable):

- ☐ Communication
- ☐ Data Entry
- ☐ Transportation

SFC OPTN Hearing Exhibit B.19

- Packaging/Shipping
- Labeling
- Recovery Procedure/Process
- Transplant Procedure/Process
- Testing
- Organ Allocation/Placement
- Other (please describe in description field below)

Attachments

Choose File | No file chosen

Maximum File Size 20MB

Correspondence/Comments

Add

Comment	Date	User

Save (/PatientSafety/Situations/UpdateDetails?CTXT=tv7nhlZPMWyvTBFUbclmcyoQ2B1vllZK56nIT9LacJ3Vl%2F4FAKtrHQ%3D%3D) Print (/PatientSafety/Situations/Details
print=Y&id=101520&TRKR=tv7nhlZPMWyvTBFUbclmcyoQ2B1vllZK56nIT9LacJ3Vl%2F4FAKtrHQ%3D%3D&CTXT=tv7nhlZPMWyvTBFUbclmcyoQ2B1vllZK56nIT9LacJ3Vl%2F4FAKtrHQ%3D%3D)

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[redacted] [redacted] [redacted]

CONFIDENTIAL MEDICAL PEER REVIEW

SFC OPTN Hearing
Exhibit B.20

UNOS DONATE LIFE

Member Quality Department: Non-Routine Intake and Triage Form

Staff Completing Intake: [redacted]

Mode of Notification (e.g., member complaint, self-report, observation on site survey): Member complaint

Method of Intake (e.g., phone call, site survey, PSP): [redacted]

Receipt Date (UNOS): 11/28/18 **Receipt Time (UNOS):** 8:30 am

Receipt Date (MQ): / / **Receipt Time (MQ):** /

Intake Date (MQ IH Staff): / / **Intake Time (MQ IH Staff):** /

Case Details

Reporting Institution or Individual: NCCM LU recipient has died

Subject of Report (Institution or Individual): SCOD

Brief Description of Issue: [redacted] 11/27/18. HR recipient (ABO B) tx w heart from hemodilated "O" donor. Pt's ABO was indeterminate; following were O bA after massive transfusion. HR stiffened tedematous right after off xc, had to be converted to ECMO. They notified SCOD at 0300 on 11/28/18. They + panel-reactive & found donor to be ABO A.

Section A

1. Does the presenting issue meet any of the criteria listed on Attachment I of this document? ☒ Yes ☐ No AdmA 11/24 Pronovo 11/25 xc = 11/27
   a. If yes, describe issue below and proceed to question 2.
      #6 – Any Complaint issue...
   b. If no, proceed to question 2.
2. Was there direct and specific harm to an identified patient or patients? ☒ Yes ☐ No
   a. If yes, i. Identify the patient or patients: HR + other patients got ABO incompatible tx.
      ii. Specify the harm (e.g., diagnosis, injury, condition):
      iii. When did the harm occur (date, time)? 11/27/18
      iv. Then, skip to question 4.
   b. If no, proceed to question 3.
3. Was there high potential for direct and specific harm to an identified patient or patients? ☒ Yes ☐ No
   a. If yes, i. Identify the patient or patients:
      ii. Specify the potential harm: Same as above

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iii. When did this potential for harm take place? _____

iv. Then, to question 4.

b. If no, proceed to Section B.

4. Was there a specific member action or inaction that led to the harm or the potential for harm? ☒ Yes ☐ No

a. If yes, i. State the action or inaction (be specific): ABO testing on mass transfusion

ii. Proceed to question 5.

b. If no, assign to MEDIUM PRIORITY and proceed to Case Disposition section of this form.

5. Is there a reasonable concern that this situation could recur in the near future (i.e., within 1 week)? ☐ Yes ☒ No

c. If yes, assign to HIGH PRIORITY and proceed to Case Disposition section of this form.

d. If no, assign to MEDIUM PRIORITY and proceed to Case Disposition section of this form.

Section B

6. Does the situation or issue represent a threat to the integrity or trust in the OPTN? ☒ Yes ☐ No

a. If yes, report issue within 4 hours to your Manager through direct communication (phone or face-to-face). Then, proceed to the Case Disposition section of this form.

b. If no, proceed to question 7.

7. Is there suspicion or allegation of criminal activity? ☐ Yes ☒ No

a. If yes, report issue immediately to your Manager through direct communication (phone or face-to-face). Then, proceed to the Case Disposition section of this form.

b. If no, proceed to question 8.

8. Is there media involvement? ☐ Yes ☒ No

a. If yes, send an e-mail notification to your Manager AND the DEQ Assistant Director (Audit & Monitoring).

b. If no, assign LOW PRIORITY and proceed with Routine Investigation Pathway.

Case Disposition

Intake Form must be completed within 2 hours of receipt despite assigned priority.

Initial Category Assigned:

☐ High (Your manager must be notified through direct communication immediately.)

☒ Medium (Your manager must be notified within 4 hours of intake.)

☐ Low (Your manager must review a copy of this form within 1 week of intake.)

☐ Other (Your manager must be notified immediately.)

☐ Case Referred (see list) Group: _____

Assigned Case Lead: [redacted]

Potential Policy/Bylaw Violations (if applicable): TBD

Management Review (required for all case types):

Management Notified (Date/Time): 11/28/18 9:30 am in person Management Initials: [redacted]

(In manager's absence, notify your Assistant Director.)

Category Assigned:

- ☐ High (AD/Director to notify Executive Director and Assistant Executive Director immediately. Preliminary investigation complete within 24 hours.)
- ☑ Medium (AD/Director to notify Executive Director and Assistant Executive Director within 3 days of receipt of intake.)
- ☐ Low (DEQ A.D.-Audit & Monitoring, OPTN Exec. Director and HRSA will be provided a listing of all cases designated "low" priority status on a monthly basis.)
- ☐ Other (Notify executive-level UNOS leadership within two business days of intake)

Assistant Director Review (required for high, medium and other):

Assistant Director notified (Date/Time): _____ Assistant Director Initials: _____

Agree with previously assigned category? ☐ Yes ☐ No

If no, reassigned category: ☐ High ☐Medium ☐Low ☐Other

OPTN Executive Director notified (Date/Time): _____

HRSA Notified (Date/Time): _____

☐ Included in monthly HRSA report? Month: _____

☐ Quality Inspection Complete? Date: _____ Initials: _____

Attachment 1: HRSA-Reported Events

Events that should be reported to the OPTN leadership within 24 hours of issue intake:

1. A transplant of the wrong organ into an organ recipient
2. A near-miss transplant of the wrong organ into an organ recipient
3. A transplant into the wrong organ recipient
4. A near-miss transplant into the wrong organ recipient
5. A suspected (or confirmed) human immunodeficiency virus (HIV) transmission from a donor (deceased or living) to a transplant recipient.
6. Any complaint, issue, or concern that may pose a serious or time-sensitive threat to public health or patient safety (including failure to provide a safe environment to patients), regardless of whether there is a suspected or actual violation of OPTN policy or the OPTN final rule.
7. A living donor death, regardless of the time period after surgery and regardless of the cause of death.
8. Failure of a native organ in a living organ donor.
9. Evidence of an attempt to deceive the OPTN or the Department (e.g., falsifying medical records).
10. Use of a device for a condition, diagnosis, or procedure that is contraindicated by the Food and Drug Administration (FDA).
11. Any "Never Event," as included in the Centers for Medicare and Medicaid Services' (CMS) policies for selected hospital-acquired conditions (HAC's), in an OPTN member hospital that impacts transplant patients or living organ donors (including those under evaluation for living organ donation).

With respect to Items 1 and 2, an event should be considered a "near-miss" if the error is not caught before the recipient is brought to the surgery holding area. With respect to Items 1,2,3, or 4, errors that might lead to the transplant of the wrong organ or patient, or near-miss events, may include documentation errors involving donor ABO, donor identification information (ID), intended recipient name or other ID, packaging or labeling errors (of organ, tissue specimens, blood) involving donor ABO, donor ID, intended recipient name or other ID, and/or the organ type, or an organ that goes to the wrong destination.

Events that should be reported to the OPTN leadership within 1 business day (Excludes Saturday, Sunday and holidays):

1. Suspected or significant potential of (non-HIV) disease transmission from a donor to a transplant recipient.
2. Any sanction taken by a state medical board or other professional body against a transplant professional working for an OPTN member.

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[redacted]

From: [redacted]@sharinghopesc.org>
Sent: Thursday, November 29, 2018 1:00 PM
To: [redacted]
Cc: [redacted]
Subject: We Are Sharing Hope SC - SCOP Containment Plan - Incompatible ABO - Donor ID [redacted]

[redacted]

Below is the containment plan we discussed yesterday for the case reference above. If you have any questions. Please do not hesitate to contact me.
Lorraine

We Are Sharing Hope SC Containment Plan to the ABO Incident
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.

[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

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[redacted]

From: [redacted]
Sent: Monday, December 3, 2018 8:42 AM
To: [redacted]
Cc: [redacted]
Subject: Secure: HRSA 24-Hour Reportable Event - ABO Incompatible Transplant

Good morning:

I wanted to share the good news that the heart transplant recipient in the case was able to be transplanted on Sunday, 12/2/18.

[redacted]
Safety Analyst

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[redacted]

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CONFIDENTIAL MEDICAL PEER REVIEW CONTENT/CONFIDENTIALITY STATEMENT

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From: [redacted]
Sent: Wednesday, November 28, 2018 1:46 PM
To: [redacted]
Cc: [redacted]

[redacted]

Subject: Secure: HRSA 24-Hour Reportable Event - ABO Incompatible Transplant

HRSA Colleagues:

On November 28, 2018, the Member Quality Department received a report of four ABO incompatible transplants involving organs from a single donor allocated by OPO 02412N. Per Wakefield Criteria #6 (any issue that may pose a serious threat to patient safety) we are reporting this event to you. A summary is provided below of what we know about this event as of this moment:

Case Facts:

Donor ID#	[redacted]
Organs Transplanted	Bilateral Lung, Heart, Liver, Left Kidney
Organs Allocated but Not Transplanted	Pancreas, Right Kidney
Date of Donor Hospital Admission	11/24/18
Date Declared Brain Dead	11/25/18
Date of Organ Procurement	11/27/18
Transplant Dates	11/27/18 and 11/28/18
Date OPO Alerted	11/28/18
Date UNOS Alerted	11/28/18
Donor ABO Used in Allocation	O
Donor Correct ABO	A1

Available Case Information:
OPO 02412N managed a donor who received multiple units of blood products as part of a massive transfusion protocol. The first ABO typing performed was indeterminate, but the second and third typings indicated an ABO of O. Organs were allocated as O. The heart center transplanted the heart into an ABO B recipient; upon release of cross clamp surgeons saw immediate signs of rejection and the heart recipient was placed on ECMO. The left kidney recipient, ABO O, was transplanted and is "not doing well." The lung transplant recipient, ABO O, was transplanted, had acute rejection, was put on ECMO, and died. The liver recipient, ABO O, shows no signs of rejection and the surgical team feels optimistic that they can manage the transplant. It appears that the pancreas center and right kidney center did not proceed with transplant due to being informed of the ABO issue or via finding the ABO of A1 independently.

Donor Analysis:
The donor was a 24-year-old female who died from a motor vehicle accident. The donor was identified as PHS Increased Risk due to hemodilution. The initial indeterminate ABO was not mentioned in DonorNet.

I will provide any additional significant updates as they are identified.

Please let me know if you have any questions or concerns.

[redacted]
Safety Analyst

UNOS UNITED NETWORK FOR ORGAN SHARING

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[redacted]

[redacted]

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[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.DonatetoLifeSC.org

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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.

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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

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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.**

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	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		

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	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/		

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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.

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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

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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]

[redacted]

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CONFIDENTIAL MEDICAL PEER REVIEW

March 13, 2019

VIA SECURE EMAIL

[redacted]
CEO/President
OPTN/UNOS Representative
We Are Sharing Hope SC
[redacted]

[redacted]
Medical Director, Organ Division
We Are Sharing Hope SC
[redacted]

Dear [redacted]

As you know, Membership and Professional Standards Committee (MPSC) leadership, including the Vice Chair, Chair of the Performance Analysis and Improvement Subcommittee (PAIS), and Chair of the Policy Compliance Subcommittee (PCSC), along with the OPTN President reviewed We are Sharing Hope's (SCOP) root cause analysis, containment plan and corrective actions regarding donor [redacted]'s ABO determination that led to incompatible transplants. After this review, the leadership group requested additional specific information and requested that the program participate in an informal discussion to discuss this case.

SCOP participated in an informal discussion on January 28, 2019 with an MPSC subcommittee. The MPSC met on February 27, 2019, and reviewed submitted documentation and the subcommittee's recommendations.

Based on its review, the MPSC approved the following:

> RESOLVED, that the Membership and Professional Standards Committee issues a Notice of Noncompliance to We are Sharing Hope for violation of Policy 2.6.A (Deceased Donor Blood Type Determination).

The Committee voted 29 For; 0 Against; and 1 Abstention.

[redacted]

[redacted]
We Are Sharing Hope SC
March 13, 2019
Page 2

CONFIDENTIAL MEDICAL PEER REVIEW

The MPSC also requests that SCOP submit the following documentation for MPSC review:

- A log of all cases escalated for Medical Director review identifying:
  - The trigger that escalates the case for review
  - Steps taken by the AOC and Medical Director to resolve the case
  - The case resolution

The MPSC also suggests that SCOP consider looking at additional cases of unexpected graft failure. SCOP may want to look at those cases, even if they did not meet their criteria for review, to determine whether they may also have blood type determination issues. Please submit the requested documentation to [redacted] Compliance Operations Analyst, no later than **May 23, 2019**.

Pursuant to the above resolution, the MPSC hereby issues this Notice of Noncompliance to SCOP.

Please note, a Notice of Noncompliance is included in Appendix L of the Bylaws, which is accessible at http://optn.transplant.hrsa.gov. A Notice of Noncompliance is not an adverse action under the Bylaws but is meant to inform the member of the need to ensure continuing compliance with policies monitored by UNOS. A Notice of Noncompliance does not need approval from the Board of Directors and is not made public. UNOS will include the letter in your member compliance history, and it may be considered by the MPSC should future compliance issues arise.

Please be aware that this correspondence and all related documents and information are protected by applicable peer review statutes. Members must keep all information provided in the medical peer review processes and settings confidential. Therefore, all inquiries, deliberations, recommendations, and actions of the MPSC, Board of Directors, other committees, and Organ Review Boards must be kept confidential by members during the review process and after the matter is closed. The Board of Directors may make public certain final adverse actions as outlined in the Bylaws.

If you have any questions or concerns, or need any additional information regarding this resolution, please contact [redacted]

Sincerely,

[redacted]
Vice Chair, OPTN/UNOS Membership and Professional Standards Committee

[redacted]

Date: Wednesday, November 28 2018 09:08 AM
Subject: RE: New Safety Situation
From: [redacted]
To: [redacted]@unos.org>; [redacted]@unos.org>;

[redacted] in the OC spoke with SCOP coordinator [redacted] who states all recipient centers are aware of this event. Report is that "nobody is doing well".

From: [redacted]@unos.org>
Sent: Wednesday, November 28, 2018 9:05 AM
To: [redacted]@unos.org>; [redacted]@unos.org>
Subject: RE: New Safety Situation

FYI the donor ID for this is [redacted] The heart, liver, and left KI have been transplanted according to TIEDI.

[redacted]
Safety Analyst

[redacted]

From: [redacted]@unos.org>
Sent: Wednesday, November 28, 2018 8:55 AM
To: Patient Safety System Email Group <PatientSafetySystemEmailGroup@unos.org>
Cc: [redacted]@unos.org>
Subject: RE: New Safety Situation

This is NCCM TXC reporting an ABO discrepancy. They received a heart from an SCOP hemodiluted donor whose allocation was run with ABO "O" assignment. (The donor received massive transfusion protocol and first ABO was indeterminate). After transplant, the heart was stiff and edematous. The recipient is on VA ECMO. We are working with the Organ Center to ensure that all recipient centers have been notified of this event.
This is a low and [redacted]

From: [redacted]
Sent: Wednesday, November 28, 2018 8:30 AM
To: [redacted]
Subject: New Safety Situation

Situation ID: [redacted]
Date Reported: 11/28/2018 8:30:08 AM

Quick Link to situation details:
[redacted]

[redacted]

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CONFIDENTIAL MEDICAL PEER REVIEW

January 18, 2019

VIA SECURE EMAIL

[redacted]
CEO/President
OPTN/UNOS Representative
We Are Sharing Hope SC
[redacted]

[redacted]
Medical Director, Organ Division
We Are Sharing Hope SC
[redacted]

Dear [redacted]

As you know, UNOS' Member Quality Department staff has been reviewing the blood typing and transplant of incompatible organs from donor [redacted] The Membership and Professional Standards Committee (MPSC) leadership, including the Vice Chair, Chair of the Performance Analysis and Improvement Subcommittee (PAIS), and Chair of the Policy Compliance Subcommittee (PCSC), along with the OPTN President are reviewing the information that We are Sharing Hope SC (SCOP) has submitted to this date, in a blinded fashion. The leadership group has requested additional specific information and requested that the program participate in an informal discussion to discuss this case.

In order to facilitate a dialogue and for the MPSC to better evaluate the issue, the Committee leadership requests that SCOP participate in an informal discussion with the MPSC. This informal discussion will take place via conference call. UNOS staff will work to set up the call as soon as possible.

MPSC Concerns

The MPSC leadership was concerned by the failure of SCOP's staff and AOC to recognize the potential safety consequences of indeterminate blood typing issues. The group was concerned with the use of broad terminology such as mass transfusion and indeterminate blood type instead of firm clinical and situational triggers when determining which donor cases go for AOC and Medical Director review. Finally, the group was particularly concerned that SCOP did not

[redacted]

accept responsibility for this event and look internally to assess what OPO staff could have done to prevent this event, regardless of the actions of the donor hospital.

In an effort to mitigate the risk to patient health and public safety, the MPSC requested that SCOP immediately do the following:

- For every donor with a blood typing sample that is hemodiluted for the primary or confirmatory draw, the OPO must:
  - Send the case to the AOC and Medical Director for review prior to assigning ABO
  - Communicate to all receiving transplant centers that the ABO has been determined using a hemodiluted sample
- Using defined clinical triggers, develop an event-driven algorithm that will automatically prompt mass transfusion cases for review by the AOC and Medical Director.

These actions must be completed until an MPSC-approved protocol is in place.

The MPSC has also requested that SCOP submit the following documentation:

- An updated RCA that includes a comprehensive internal assessment of actions the OPO could have taken to prevent this type of event
- An updated corrective action plan that includes policy development and staff and leadership training regarding mass transfusions and ABO typing.

Informal Discussion Timelines

Informal discussions are described in Appendix L of the Bylaws, which can be accessed on the OPTN website at http://optn.transplant.hrsa.gov. Informal discussions are intended to provide the MPSC and member an opportunity to openly discuss the review and seek feedback. If your institution wishes to participate in the informal discussion, please submit written notification to [redacted], Compliance Operations Analyst no later than **Tuesday, January 22, 2019,** to [redacted]

The informal discussion schedule will include 10 minutes for your presentation and 15 minutes for a question and answer period with the MPSC. After the call, the group will report its recommendation to the MPSC. We will notify you of the outcome as soon as possible after the MPSC's deliberations.

Please submit any additional documentation you would like the participants to review prior to the informal discussion as soon as possible. The MPSC will provide a deadline for additional documentation after the call.

Please be aware that this correspondence and all related documents and information are protected by applicable peer review statutes. Members must keep all information provided in the medical peer review processes and settings confidential. Therefore, all inquiries, deliberations, recommendations, and actions of the MPSC, Board of Directors, other committees, and Organ Review Boards must be kept confidential by members during the review process and after the matter is closed. The Board of Directors may make public certain final adverse actions as outlined in the Bylaws.

[redacted]
We Are Sharing Hope SC
January 28, 2019
Page 3

CONFIDENTIAL MEDICAL PEER REVIEW

If you have any questions or concerns, or need any additional information regarding this issue, please contact [redacted]

Sincerely,

[redacted]
Vice Chair, OPTN/UNOS Membership and Professional Standards Committee
[redacted]

	[redacted] - Donor [redacted]	SCOP - Donor [redacted]
Donor transfusion status	• Received massive transfusion protocol. OPO reports 21 units within first 10 hours of admission.	• Received massive transfusion protocol. OPO reports 26 units during attempt at life saving surgery.
HRSA 24 hour notification?	No	Yes
Left kidney	• Transplanted into ABO A recipient • Graft functioning	• Transplanted into ABO O recipient • Graft functioning
Right kidney	• Transplanted into ABO O recipient • Hyperacute rejection • Patient explanted and alive	• Discarded after ABO error found
Liver	• Transplanted into ABO O recipient • Patient plasmapheresed • No signs of rejection and alive	• Transplanted into an ABO O recipient • Graft functioning
Lungs	• Not transplanted	• Transplanted into ABO O recipient • Hyperacute rejection • Recipient died the next day
Heart	• Not transplanted	• Transplanted into ABO B recipient • Hyperacute rejection • Explanted, re-transplanted six days later with graft functioning
Intestine	• Not transplanted	• Not transplanted
Pancreas	• Not transplanted	• Allocated to an ABO O recipient • Receiving center found ABO error while performing confirmatory typing • Not transplanted
Donor ABO Typing #1	• 9/23/18, pre-transfusion sample • ABO: A	• 11/24/18, post-transfusion sample • ABO: Forward O, Reverse A • Reverse typing not communicated to OPO
Donor ABO Typing #2	• 9/24/18, post-transfusion • ABO: O	• 11/25/18, post-transfusion sample • ABO: Forward O, Reverse A • OPO aware of discrepancy
Donor ABO Typing #3	• 9/25/18, post-transfusion • ABO: Forward O, Reverse A	• 11/25, post-transfusion sample • ABO: Forward O, Reverse O • Considered confirmatory typing of ABO Typing #1
Donor ABO Typing #4	• 9/27/18, post-transfusion • ABO: O	• Not applicable
Why Donor Allocated as ABO O?		• OPO had two separate blood draws that indicated ABO O • Issue of massive transfusion was not addressed as possible cause of ABO O result
Were centers informed of ABO discrepancies upon organ acceptance?		• No - OPO did not consider discrepant as they had confirmatory testing.
Was ABO discussed with Medical Director?		• No
Was there a credible threat for media involvement?		• Yes

Date: Saturday, January 26 2019 08:51 PM
Subject: SCOP Documents
From: [redacted]@sharinghopesc.org>
To: [redacted]@unos.org>;
CC: [redacted]@sharinghopesc.org>;
Attachments: SHSC Response to Jan 18 MPSC Letter - With Attachments.pdf; MPSC Presentation 01.28.2019.pptx; SCOP MPSC Response Letter 01.25.2018.docx

[redacted]

Attached you will find:

- SCOP MPSC Response to letter received on January 18, 2019 with attachments
- SCOP Informal Discussion Pre-Discussion Letter –outlining attendees, contact information and attached powerpoint presentation for the informal discussion.

If you have any questions please call me on my cell at [redacted]

[redacted]
Director Quality Systems

We Are Sharing Hope SC
[redacted]

Give the Gift of Life
Register to Be an Organ Tissue Donor at [redacted]

[redacted]

The Washington Post
Democracy Dies in Darkness

Thousands of lives depend on a transplant network in need of 'vast restructuring'

White House's U.S. Digital Service found that the technology that matches donated organs to patients has failed repeatedly

By Joseph Menn and Lenny Bernstein

Updated July 31, 2022 at 12:00 p.m. EDT | Published July 31, 2022 at 6:00 a.m. EDT

The system for getting donated kidneys, livers and hearts to desperately ill patients relies on out-of-date technology that has crashed for hours at a time and has never been audited by federal officials for security weaknesses or other serious flaws, according to a confidential government review obtained by The Washington Post.

The mechanics of the entire transplant system must be overhauled, the review concluded, citing aged software, periodic system failures, mistakes in programming and overreliance on manual input of data.

In its review, completed 18 months ago, the White House's U.S. Digital Service recommended that the government "break up the current monopoly" that the United Network for Organ Sharing, the nonprofit agency that operates the transplant system, has held for 36 years. It pushed for separating the contract for technology that powers the network from UNOS's policy responsibilities, such as deciding how to weigh considerations for transplant eligibility.

About 106,000 people are on the waiting list for organs, the vast majority of them seeking kidneys, according to UNOS. An average of 22 people die each day waiting for organs. In 2021, 41,354 organs were transplanted, a record.

UNOS is overseen by the Health Resources and Services Administration (HRSA), but that agency has little authority to regulate transplant activity. Its attempts to reform the transplant system have been rejected by UNOS, the report found. Yet HRSA continues to pay UNOS about $6.5 million annually toward its annual operating costs of about $64 million, most of which comes from patient fees.

"In order to properly and equitably support the critical needs of these patients, the ecosystem needs to be vastly restructured," a team of engineers from the Digital Service wrote in the Jan. 5, 2021, report for HRSA, which is part of the Department of Health and Human Services.

"There are little to no incentives for … UNOS … to ever modernize the operations of the [system] and improve the current processes or technology, and the government has very little leverage," the investigators wrote.

UNOS considers its millions of lines of code to be a trade secret and has said the government would have to buy it outright for $55 million if it ever gave the contract to someone else, according to the report.

Transplant doctors have complained for years about archaic aspects of the technology for sharing data and getting organs to the right place as quickly as possible.

“When nearly 100 percent of hospitals use electronic records, the notion that we rely on human beings to enter data into databases is crazy. It should be 85 to 95 percent automatic,” said University of California at San Francisco surgery vice chair Ryutaro Hirose, a former chair of the UNOS liver transplant policy committee. “We could concentrate more on improving patient care.”

Hirose said he had been forced to turn to travel sites such as Expedia to make plans for transporting organs. “With DoorDash, I know where my food is. That should at least be the case for a lifesaving organ,” he said.

Carrie Frenette, who until December was medical director of liver transplants at Scripps Green Hospital in the La Jolla neighborhood of San Diego, echoed that complaint. “You have to have your coordinator at your center arrange transportation, and there is no help from UNOS,” Frenette said.

“We had a very sick woman in the ICU on life-support systems. We finally got an organ offered, but there were difficulties in getting the surgeons to her and getting the liver back, and a week later she died,” Frenette said.

In an interview, UNOS chief executive Brian Shepard said the nonprofit was improving tracking and had a travel-planning app in development.

Shepard said the Digital Service report “reads more like an op-ed” than a paper based on thorough research. He said the transplant system is secure and effective.

Yet leaders of the Senate Finance Committee, which has scheduled a hearing on the system for Wednesday, grew so alarmed during a closed-door briefing earlier this year that they warned officials at the Department of Homeland Security and intelligence agencies in a letter seen by The Post that they had “no confidence” in the security of the transplant network. They asked the White House to intervene to protect it from hackers.

“We request you take immediate steps to secure the national Organ Procurement and Transplantation Network system from cyber-attacks,” the committee chair, Sen. Ron Wyden (D-Ore.), and Sen. Charles E. Grassley (R-Iowa) wrote to Federal Chief Information Officer Clare Martorana in February.

The senators wrote that “no one working for the federal government has ever examined the security of this system” and the government “has not imposed any cybersecurity requirements on UNOS.” The Digital Service report also noted that government experts have never been allowed to inspect the computer code that runs the complex transplant system.

An official in the administration’s Office of Management and Budget, which oversees the Digital Service, said OMB has worked with Health and Human Services on steps to “ensure the cybersecurity” of the transplant system.

HRSA said it was still working with the Digital Service and other experts. “We are consulting with the United States Digital Service to modernize the Network’s IT and we have sought best insights from patients, academics, tech experts, and clinical leaders,” it wrote in a statement.

UNOS's Shepard stressed that the Digital Service report was still in draft form. But a former White House official involved in the review, who spoke on the condition of anonymity because he was not authorized to discuss the Digital Service findings, said that the report is normal; such reports are routinely labeled as "pre-decision" drafts because they are prepared for cabinet secretaries and their deputies who must then choose to act.

That label also exempts the reports from Freedom of Information Act requests, and UNOS said it had been unable to obtain the document until The Post provided the text.

Shepard, who is stepping down in September, said his organization is audited yearly by HHS. He said that if officials visit the UNOS office, they can review specific chunks of the source code.

"The code is extremely large," Shepard said. "They can come in and ask for specific pieces."

UNOS said it was audited in 2020 by HRSA and last year by the office of the HHS inspector general, which is checking the security controls. A former HHS official familiar with the transplant system said the department ran through a checklist of questions but never won access to the system itself.

UNOS said in a statement that its refusal to turn over the full code is part of "an important balance: providing HRSA and other auditors the access they need to ensure the system's security while limiting wider access in order to safeguard patient data and protect UNOS' intellectual property."

UNOS also said it would soon get a security penetration test by an HHS-recommended firm and a review of its "cyber-hygiene" by the U.S. Cybersecurity and Infrastructure Security Agency, the Department of Homeland Security division responsible for computer security.

UNOS oversees what is formally known as the Organ Procurement and Transplant Network, a complex collection of about 250 transplant-performing hospitals; 57 government-chartered nonprofits that collect organs in their regions; labs that test organs for compatibility and disease; and other auxiliary services.

Located in Richmond, UNOS sits at the center of the system. It is the only organization to ever hold the 36-year-old contract to run the operation, currently a multiyear pact worth more than $200 million, funded mainly by fees patients pay to be listed for transplants.

UNOS oversees controversial policies that determine which patients have priority for lifesaving kidneys, hearts, livers and other organs. It reviews mistakes by members of the network and maintains the waiting list for organs. And it runs the complex technology that connects the entire enterprise.

Part of UNOS's job is to monitor the performance of organ procurement organizations (OPOs) and hospitals where transplants are performed. When either is reported to have needlessly wasted an organ or endangered patient safety, UNOS is supposed to look into the incident. It can provide advice to the organization on how to improve or impose a variety of sanctions.

Critics have long said UNOS does little with many of these complaints, leaving the problems that caused them unresolved. Its findings and the work of its investigators are not made public.

Only the government, however, can revoke an OPO's license to operate. That has never happened in the history of the transplant system.

More than 20 percent of all kidneys procured for transplant in the United States are not used, according to data from the Scientific Registry of Transplant Recipients. That rate reached a new high in 2020, when 21.3 percent of procured kidneys were not transplanted, a registry report found. The reasons are in dispute, with members of the network often blaming each other.

European countries report much lower "discard rates" for kidneys, according to various studies. France had a kidney discard rate of 9.1 percent from 2004-2014, a 2019 study found. The United Kingdom has a rate ranging from 10 to 12 percent. Eurotransplant, a consortium of eight countries including Germany, reported a rate of about 8 percent.

Some of the 57 OPOs also fail to meet government standards for their main job — collecting organs. After decades of allowing them to calculate and report their own compliance data, the government in 2019 took steps to hold the worst of them accountable.

As for UNOS itself, a comprehensive study requested by Congress was conducted by the National Academies of Sciences, Engineering and Medicine. In February, it came to one of the same conclusions as the Digital Service, recommending splitting the information technology infrastructure into a separate contract or requiring modernization when UNOS's current contract comes up for rebidding, likely in 2023.

"HHS should ensure that the OPTN uses a state-of-the-art information technology infrastructure that optimizes the use of new and evolving technologies to support the needs and future directions of the organ transplantation system," the Academies wrote, adding that the system "could save additional lives" if it acted more cohesively with better oversight.

The Digital Service investigators found that the critical computers connecting the transplant network have crashed for a total of 17 days since 1999, with one February 2021 outage lasting about three hours, according to follow-up work conducted by the investigators. That's a critical problem when organs can lose vitality after as little as four hours. Shepard blamed a firewall failure for the three-hour crash, adding that there have been no unplanned disruptions since then.

In another case, the former official in the Department of Health and Human Services said, UNOS allowed a programming error to push some lung patients lower on the priority list than they should have been. The mistake was eventually caught by a different federal contractor analyzing patient data, he said.

UNOS officials said they had gone back to assess the impact of the mistake and found that it had delayed some matches but that all the patients had eventually gotten one.

As portrayed in the report and interviews with current and former government officials, the technology that runs the transplant system is not only far behind current standards but also unlikely to catch up. That's because UNOS owns the system under an unusual contract with the Department of Health and Human Services that prevents meaningful oversight.

The 1984 National Organ Transplant Act established the transplant network as a "quasi-governmental agency" — with UNOS in mind — run by a nonprofit under a single contract, the Digital Service report said.

That "leaves the government with only a monitoring function to make sure the OPTN contractor follows the statute, rather than the kind of oversight authority" found in more traditional relationships between government and contractors, the report said. Any change in the way the system operates likely would require Congress to amend the 1984 law.

In its statement to The Post, HRSA said it was "committed to using all available tools to modernize the Organ Procurement and Transplantation Network, including leveraging the upcoming contracting process to increase accountability." It also said it would "welcome the opportunity to work with Congress to update the nearly 40-year-old National Organ Transplant Act."

UNOS has touted ambitious efforts to upgrade its technology, but most were quietly abandoned when they ran into problems, the report said.

UNOS's shortcomings are compounded by HRSA's own failings. The agency lacks technical expertise, can't force the network to turn over data, and is so concerned about upsetting the nonprofit that it has been reluctant to push for more intensive demonstrations of the system, according to the report and interviews. That allows UNOS "to wiggle through and around most new contract requirements for the [transplant network's] technology by hand-waving at change with technical jargon, while making no substantive progress," the Digital Service report said.

"There are no requirements, or mechanisms to create requirements, in the current contract" that would force UNOS to upgrade its technology, the report said. "UNOS knows this, and it is why when asked directly about their timeline for modernization, they point at HRSA and just say, 'We'll do it when they tell us to.' "

UNOS has not allowed anyone in government to analyze its code base, instead providing only the English-language description of it, known as pseudocode, officials said. That surprised Digital Service analysts; it was the only time that its engineers' request to inspect code used by government agencies and contractors has been refused on nearly 100 occasions, according to the former White House adviser who was involved but not authorized to speak.

UNOS also "has at times even threatened to walk away and continue operating the [transplant network] without a contract, despite the fact that it would be illegal for them to operate such a network independent of a government contract," the Digital Service wrote. That has kept HRSA "hesitant about pursuing avenues for real change in this program," it added.

UNOS said that claim twisted a conversation during contract talks years ago in which it tried to assure the government that it would keep operating even if the old deal expired, rather than harm patients. But the former HHS official said the department saw the statement as a hardball tactic to put pressure on the government to meet UNOS's terms.

Among the key technical findings of the report was that the vast majority of UNOS's operation was running on a local data center instead of on the kind of cloud computing systems that have become the norm for most large businesses and public agencies. Switching to a cloud computing system would reduce system lags and downtime, allow greater automated access, and add computing power to support machine learning, the Digital Service said.

UNOS said that it used both public and private cloud architecture, with the latter in two physical locations.

The report found that the system still requires manual data entry that can lead to mistakes or narrow the timing window for successful organ matches.

Shepard said that in some cases hospitals had not modernized enough to automate data entry.

The Digital Service report also said the organizational structure of the software that matches donors with patients is so clunky that even a single change in priority policy can take a full year to be reflected in the code. Shepard acknowledged that some shifts take that long**.**

The Digital Service team also accused UNOS of misplaced priorities in its approach to technology.

“They have placed on their product roadmap things like artificial intelligence, mobile delivery of functionality and advanced predictive modeling,” the team wrote. “Where UNOS should be focused on getting the basics right for the core functionality before they layer in additional complexity … they instead seem intent on adding shiny technology and distracting program stakeholders.”

Several former officials familiar with the transplant system confirmed the Digital Service’s description of UNOS’s resistance to government oversight. Robert P. Charrow, the HHS general counsel during the Trump administration, called the situation “the most topsy-turvy relationship I’ve ever seen.”

In its report, the Digital Service said it identified three other unspecified organizations with “clear capabilities” to take over UNOS’s technology.

But potential competitors for the contract are waiting to see how HRSA writes the requirements in a new bidding document. The last time the contract was up, in 2018, potential applicants ultimately were dissuaded by requirements that HRSA included that called for bidders to have at least three years of experience managing transplant projects of similar complexity — a description that fits only UNOS or a group running a transplant system in another country.

When the new request for proposals will be issued is uncertain. The government has so far issued only a “request for information,” a step before it calls for bids. That document describes a $248 million deal (presumably over multiple years), with $27.7 million coming from the government and the rest from fees patients pay to be listed for transplants.

Any transition to another vendor would cost more than $71 million, the Digital Service report estimated, including $55 million to purchase the current systems. The Digital Service called the figure “exorbitant” and said “the government should never have to be in a position to make the purchase of the existing systems” in order to modernize technology.

Even so, said the former White House adviser involved in the review, the government could recoup that much in a single year by improving the technology involved.

And for the same expenditure as now, according to the former HHS official not authorized to discuss the contract publicly, “You would be hard pressed to think you couldn’t at least get 5 percent better, which would be thousands of transplants.”

Todd C. Frankel contributed to this report.

EXHIBIT D

The Washington Post
Democracy Dies in Darkness

70 deaths, many wasted organs are blamed on transplant system errors

An investigation by the Senate Finance Committee blamed the fatalities on errors in screening organs for disease, blood-type mix-ups and other mistakes

By Lenny Bernstein and Todd C. Frankel
August 3, 2022 at 2:30 p.m. EDT

Seventy people died and 249 developed diseases after mistakes in the screening of organs they received in transplants, a Senate committee reported Wednesday after an investigation that found widespread deficiencies throughout the U.S. organ transplant system.

Testing errors and overlooked communications allowed the transmission of cancer, a rare bacterial infection and other diseases, the Senate Finance Committee found in its review of hundreds of thousands of pages of subpoenaed documents and other material that formed the basis of the two-and-a-half-year investigation.

The errors included failures to identify disease in donor kidneys, hearts and livers, as well as mix-ups in matching blood types and delays in blood and urine tests that were not completed before transplant surgeries occurred, the investigators concluded in a report obtained by The Washington Post.

The Senate committee partly blamed lax oversight of organ procurement organizations (OPOs), the regional nonprofits responsible for collecting donated organs, by the United Network for Organ Sharing, the Richmond-based contractor that oversees the system. It listed as problems careless treatment of donated organs, organs lost in transit, and technological issues.

In 2020, the investigation found, two healthy kidneys were accidentally thrown in the trash in Indiana. In 2015, an airline temporarily lost a donated kidney that was supposed to be shipped from South Carolina to Florida — causing the transplant surgery to be canceled and the organ discarded. In 2017, another kidney was misplaced and missed a flight from South Carolina to California, leading to another canceled transplant, but the organ was used by a local transplant team.

A UNOS spokesman said the organization could not respond to a report that its officials had not yet seen but provided a copy of testimony by UNOS chief executive Brian Shepard prepared for delivery at a Wednesday afternoon hearing of the committee. Shepard is stepping down in September.

“Ours is a complex system; one that is dedicated to continuously improving, monitoring and adapting; one that involves thousands of people coming together every single day across the country in order to save lives,” the testimony said. “It is a system Congress set in motion nearly forty years ago, and which, thanks to the decisions and expertise of those who laid the foundation, allows us to best serve patients in need of a transplant.”

The Association of Organ Procurement Organizations declined to comment.

The review provides a rarely seen level of detail into the operations of a system with seemingly little regulatory oversight, where strict privacy rules and legal restrictions typically limit the amount of information available to outsiders and whose successes largely have been trumpeted since the first successful transplant in 1954.

The Senate report examined 1,118 complaints filed from 2010 to 2020 with UNOS. The death toll from failed organ screenings — detailed in a 2016 UNOS report handed over to Senate investigators — covered a shorter time period, 2008 to mid-2015.

The deaths and illnesses were a tiny fraction of the 174,338 organs transplanted in that seven-year period. But “this data illustrates the lethality of diseases contracted during a transplantation and the need for exacting scrutiny of such transmissions,” the committee wrote in a 60-page memo prepared for the Wednesday afternoon hearing.

The Senate report is the most recent government study to find serious weaknesses in the transplant system, which is funded primarily by fees charged to patients awaiting transplants. A confidential government report by the United States Digital Service, completed 18 months ago, called for the technology that powers the system to be completely overhauled. It cited aged software, periodic system failures, mistakes in programming and overreliance on manual input of data, The Washington Post reported Sunday.

In February, a study by the prestigious National Academies of Sciences, Engineering and Medicine found the transplant system to be inequitable, with unexplained performance differences across the system. It also said that 1 in 5 procured kidneys is never transplanted.

An estimated 106,000 people are awaiting transplants in the United States. About 22 die every day awaiting a transplant, according to the National Academies. In 2021, 41,354 organs were transplanted, a record.

The committee criticized UNOS for poor oversight of the 57 OPOs. It found that UNOS staff referred 40 percent of the 1,118 patient safety complaints they received between 2010 and 2020 to the organization’s oversight panel, the Membership and Professional Standards committee. Of those, one resulted in probation — a public designation, according to UNOS’s website, that a member of the network is under a corrective action plan “for noncompliance or a serious lapse in patient safety or quality of care.”

Three complaints resulted in a “peer visit”; 63 resulted in letters of warning or reprimand; 298 led to notices of noncompliance or uncontested violation; and 68 were closed with no action.

The complaints covered all parts of the network, not just OPOs. Only the government can revoke an OPO’s right to gather organs, but that has never happened in the history of the transplant system, according to the report.

The OPOs are nonprofit organizations overseen by the Centers for Medicare and Medicaid Services, part of the Department of Health and Human Services. Each holds a monopoly to collect organs and human tissue in a specific region of the country, where its employees work with families at hospitals to obtain consent. The OPOs also are responsible for screening organs and, in most cases, arranging to send them to transplant hospitals as quickly as possible.

Kidneys, which make up more than 80 percent of organs transplanted, usually are transported by plane, under controlled conditions. Surgeons will often retrieve hearts, livers, lungs and other less common organs themselves. In 2020, 21.3 percent of procured kidneys were not transplanted, according to the Scientific Registry of Transplant Recipients. The reasons are in dispute, with members of the transplant network often blaming each other.

The Senate committee study recommended that the government create competition for UNOS, which has held the contract to run the transplant network for the entire 36 years of the system's existence. It also suggested awarding a separate contract for the transplant system's technology; increasing "transparency and accountability for chain of custody and transportation of organs;" and increasing accountability for lost, damaged and delayed organs.

Among the results of organ mistakes, the documents show, were canceled transplants. In several cases, organs already transplanted had to be removed. Some patients were able to find other organs. The fates of other patients were unknown.

One patient was told in 2020 by a transplant surgeon in Wisconsin that their new heart had come from a donor who had aggressive brain cancer — a diagnosis discovered only after the transplant — so they "likely" would die within the next three years, according to records. The documents do not say what happened to the patient.

In 2018, confusion over one organ donor's blood type in South Carolina led to four separate transplant surgeries with incompatible recipients, the documents show. The man who received the donor's lungs died the next day, after his body apparently rejected the organ. Surgeons were forced to remove another patient's transplanted heart for the same reason. The patient went back on the organ wait list and soon found another heart. Other patients with the donor's liver and kidney survived. But another kidney and the pancreas were thrown out once the blood mismatch was uncovered.

Matching a donor's blood type with the recipient's is often essential for avoiding organ rejection. It is normally a simple test. But blood typing can be complicated by blood transfusions, which are common in donors killed in car crashes or by gunfire.

The South Carolina case involved a donor who died after a motorcycle accident and had received massive blood transfusions. The transplant of her organs was coordinated by We Are Sharing Hope SC, the OPO responsible for most of South Carolina, records show.

A first test failed to pinpoint a blood type, showing signs of both type O and type A. A second test was also indeterminate. But a third test showed signs of type O. A later investigation by UNOS and the OPO found that the indeterminate results were not fully communicated to surgeons who accepted the donor's organs.

The mistake wasn't discovered until about nine hours after the donor's organs had been removed, documents show. A surgeon at another hospital who had received the donor's pancreas noted the organ was labeled type O, but a blood test run there showed type A. The surgeon was concerned and canceled the pancreas transplant.

But it was too late for the others. Four had already been transplanted. The OPO did not return requests for comment on the case.

A similar problem occurred in December 2020, when a blood-type mismatch with a single donor in California disrupted four transplants, forcing the rushed removal of three organs — including a heart — after they had been implanted.

The confusion about the donor's blood type was recognized from the beginning, with a transplant worker with Donor Network West — the San Ramon, Calif.-based OPO that handles organ donations in the San Francisco area — even calling UNOS to discuss doubts about the conflicting results, according to call notes.

The UNOS representative tried to be reassuring, adding, "all you can (do) is disclose everything." In the end, the donor's blood type officially was labeled O, but the conflicting results were noted in the computer system that coordinates transplants. All of the intended recipients of the organs had type O blood.

The donor's blood type, however, eventually was determined to be B — but only after the donor's liver, heart, kidneys and pancreas had been transplanted. All of the transplanted organs had to be removed, except the liver; doctors there had noted the confusion and took extra steps to reduce the risk of rejection.

Janice Whaley, president of Donor Network West, acknowledged in an interview that her OPO's employees should have asked more questions before proceeding. The organization has changed its policy to use a more sensitive DNA test now if there are questions over blood type.

Undetected infections can affect multiple patients, the review found. In 2017, a kidney transplant recipient in Nevada died from the rare bacterial infection tularemia just days after receiving a new organ. A patient in California who received a kidney from the same donor also was infected but survived.

Tularemia in humans is rare in the United States, with only a couple hundred cases reported in a typical year. When the Centers for Disease Control and Prevention learned about the outbreak tied to an organ donor, an agency official wrote in an email, "This is obviously a public health emergency" and expressed worry that dozens of health-care workers and transplant patients could be at risk.

Two years later, CDC and university researchers wrote in the journal Emerging Infectious Diseases that two dead rabbits found near the donor's home contained the bacteria.

Kelley McClellan, director of community development for Nevada Donor Network, declined to discuss the case until she had seen the full report.

Undetected cancer in a donor led to the discovery in 2019 of a mass on the transplanted liver of a recipient undergoing his one-year follow-up appointment. A biopsy showed the cells had originated with testicular cancer, a diagnosis that had been noted in the organ donor's autopsy report but overlooked by LifeQuest Organ Recovery Services, the Gainesville, Fla.-based group that handles transplants in the Florida Panhandle.

The recipient underwent chemotherapy and survived, according to a follow-up report.

Kathleen Giery, director of donor program development at LifeQuest acknowledged in an email that the OPO had missed the autopsy finding of cancer. After learning of the diagnosis eight months later, the OPO notified another recipient of organs from that donor, conducted an investigation and established new policies to prevent another incident.

They include having "multiple individuals review the autopsies within 24 hours, as well as any other test results," she wrote.

In another case, a heart transplant recipient learned in 2020 that staff at the OPO Life Connection of Ohio in Maumee, Ohio, had missed a positive brain cancer biopsy result from the organ's donor, records show. The donor was a woman who had died after a brain bleed at a hospital in Ohio, according to records. There were signs of a potential brain mass before the transplant. But a formal diagnosis of glioblastoma — a fast-moving and often fatal cancer — did not come until several days after the transplant.

The heart transplant patient was told about the cancer diagnosis nine weeks later by a surgeon in Wisconsin. The patient reported the incident to UNOS, noting the surgeon said they "don't know how they 'messed up' and did not catch this prior to (transplant)," records show.

In an email, Matthew Wadsworth, chief executive of Life Connection of Ohio, said results of a CT scan on the donor did not mention a mass in the brain, which means there was no indication for additional testing. The tumor was found during an autopsy, and the OPO notified UNOS and all hospitals that had accepted organs from the donor, he wrote.

"Life Connection followed its processes when evaluating the patient for donor suitability as well as the process for reporting a patient safety event," Wadsworth wrote.

A June 2020 incident in which two healthy kidneys were accidentally thrown in the trash at an Indiana hospital resulted in UNOS issuing a noncompliance order to the Indiana Donor Network, which procures organs across the state.

According to documents, a liver that had been removed from the donor was quickly packaged for delivery out of state, but the donor's kidneys were left on a table in the operating room. The three Indiana Donor Network workers responsible for the organs had left the operating room to make sure the liver departed safely.

When they returned, just six minutes later, and started scrubbing in to deal with the kidneys, they discovered hospital workers "aggressively" cleaning the operating room, according to a summary of events. The workers found the kidneys in the trash. "Hospital staff believed all that was remaining was trimmed fat to be discarded," read an internal report on the incident.

After talking with a surgeon, the transplant coordinators decided the kidneys couldn't be used.

The Indiana Donor Network had been cited by UNOS previously for errors. In 2019, it was criticized for failing to complete donor blood tests and then for failing to provide an accurate description of a donated kidney in 2018, records show. In November 2017, the group received a violation notice for late reporting of a positive test for parasitic roundworms in a donor.

The trashed kidneys led to UNOS issuing a new notice of noncompliance and requiring the transplant coordinators to craft a plan to avoid repeating the same mistake.

"Three of the citations you reference were the result of circumstances outside our organization's control and the result of errors made by others unaffiliated with Indiana Donor Network," said Mark W. Back, manager of marketing and communication for the OPO. "In each case, we worked quickly and aggressively with our partners to implement new policies and procedures to prevent future errors."

RECEIVED
Aug 17 2022
SC Court of Appeals

THE STATE OF SOUTH CAROLINA
In The Court of Appeals

Appeal from Charleston County
Court of Common Pleas
The Honorable Debra R. McCaslin, Circuit Court Judge

Appellate Case No: 2021-000487

Trial Court Case No: 2020-CP-10-02902

Michelle Cha Holliman, individually, and as Personal Representative of the Estate of Allen B. Holliman,

Respondent,

v.

We Are Sharing Hope SC, Medical University of South Carolina, United Network for Organ Sharing, Jacqueline Honig, M.D., and Darla Welker,

Defendants,

Of which We Are Sharing Hope SC and United Network for Organ Sharing are the

Appellants.

PROOF OF SERVICE

This is to certify that I have this date caused to be served a true and correct copy of the foregoing **Respondent's Motion to Dismiss Appeal for Mootness** on counsel in this action by email, pursuant to the Supreme Court's Order Re: Methods of Electronic Filing and Service Under Rule 262 of the South Carolina Appellate Court Rules dated May 6, 2022, by electronic mail, addressed as follows:

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s/John C. Moylan, III

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August 17, 2022

W Y C H E
Attorneys at Law

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SC Court of Appeals

August 17, 2022

Via E-Filing through OneDrive for Business

The Honorable Jenny Abbott Kitchings
The South Carolina Court of Appeals
P. O. Box 11629
Columbia, SC 29211

RE: Michelle Cha Holliman, individually and as personal representative of the estate of Allen B. Holliman v. We Are Sharing Hope SC, Medical University of South Carolina, United Network for Organ Sharing, Jacqueline Honig, M.D., and Darla Welker
C/A No. 2020-CP-10-02902, Charleston CP
Appellate Case No. 2021-000487

Dear Ms. Kitchings:

Enclosed for filing with your office, please find the Respondent's Motion to Dismiss Appeal for Mootness, Exhibits A-D, and Proof of Service.

All counsel of record are being served with same via electronic mail.

Sincerely,

s/John. C. Moylan, III

John C. Moylan, III
jmoylan@wyche.com

Enclosure

cc via email:

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Jean Marie Jennings, Esquire
Deborah Harrison Sheffield, Esquire
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Hugh W. Buyck, Esquire
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