



Matching organs. Saving lives.



CONFIDENTIAL MEDICAL PEER REVIEW

February 14, 2019

VIA SECURE EMAIL



Life Alliance Organ Recovery Agency



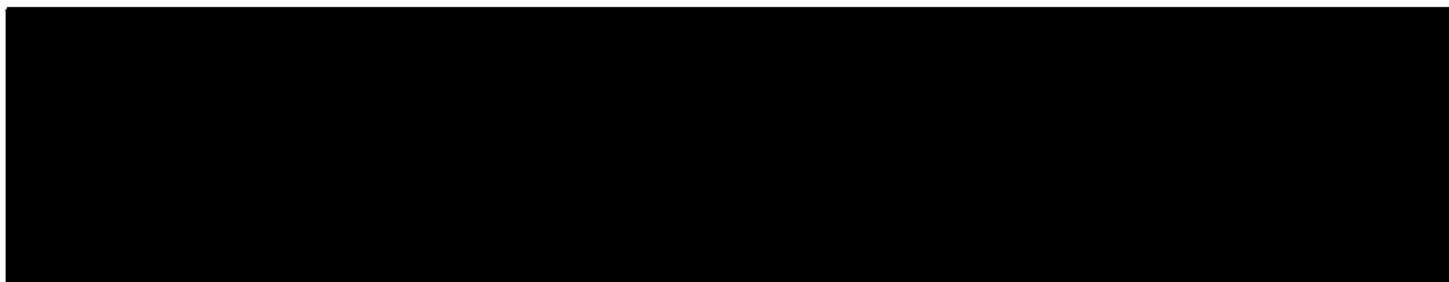
Dear [REDACTED]

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 the recovery for donor [REDACTED]. Our preliminary analysis indicates that the donor's family authorized recovery as a Donation after Circulatory Death (DCD) on November 26, 2018. The donor was pronounced brain dead on November 27, 2018. On November 28, 2018, DCD matches were executed, organs were allocated off these matches, and organ recovery occurred, however, the DCD Flowsheet indicates that hemodynamic measurements were not obtained and cardiac death was obtained via crossclamp.



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 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 this donor recovery:

- Describe the communications with the donor family prior to recovery and why they authorized DCD donation. Include what was explained to the family regarding DCD donation, brain death donation, and the family's reasons for wanting a DCD recovery. Please include case notes from the family coordinator(s) on this case.
- Pertaining to the withdrawal of life support:
 - Was the patient extubated?
 - Where did the extubation or withdrawal of life-sustaining medical support occur?
 - Were family members present for the extubation/withdrawal of life-sustaining medical support?
 - Did the family have an expectation of cardiac death prior to the initiation of the organ recovery process?
 - Were any OPO staff members or recovery personnel present during the extubation or withdrawal of life-sustaining medical support?
 - Was circulatory death achieved through cross-clamp or by natural circulatory cessation after the withdrawal of medical support?
- Explain the decision to recover the donor organs prior to cardiac death, including when that decision was made, how that decision was reached, who was involved in reaching that decision, and what information was provided to the family after that decision had been made. Provide documentation, such as case notes, of these discussions, if available.
- Did this DCD donor convert to brain death? If so, provide when that determination was made, and explain and provide documentation of the reason for not reallocating organs from brain dead match runs when the DCD donor converted to brain death.
- Was a root cause analysis or post-case review performed in response to this event? Please provide the results, if available.
- Were any corrective actions developed in response to this event? If so, include documentation that supports these corrective actions, such as revised policy, training 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.

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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 **February 28, 2019**. Responses can be sent via mail, email and/or fax. I can be contacted at [REDACTED]

[REDACTED] Thank you in advance for providing the additional information requested.

Sincerely,

[REDACTED]
Safety Analyst
UNOS Member Quality

cc: