



CONFIDENTIAL MEDICAL PEER REVIEW

March 12, 2020

VIA SECURE EMAIL

[REDACTED]
[REDACTED]
OPTN Representative
Life Alliance Organ Recovery Agency

[REDACTED]
[REDACTED]

[REDACTED]
Medical Director
Life Alliance Organ Recovery Agency

[REDACTED]
[REDACTED]

[REDACTED]
Medical Director
Life Alliance Organ Recovery Agency

[REDACTED]
[REDACTED]
[REDACTED]

Dear [REDACTED]:

As you know, the OPTN Membership and Professional Standards Committee (MPSC) met on November 7, 2019, and reviewed a report that Life Alliance Organ Recovery Agency (FLMP) recovered organs prior to asystole, despite family authorization, in violation of Policy 2.15.H (Organ Recovery). In addition, the Committee reviewed the outcome of an informal discussion conducted with the OPO on September 25, 2019, and documentation FLMP submitted in response to the discussion. Based on its review, the MPSC considered recommending the adverse action of Probation for FLMP, and requested that FLMP participate in an in-person interview at the MPSC meeting held on February 26, 2020.

Background

FLMP obtained authorization to proceed with donation after cardiac death (DCD) donation for a brain dead patient because the patient's family wanted to be in the OR when the patient's heart stopped. However, the patient's family walked out of the OR prior to asystole. Rather than proceeding with the DCD recovery for which the OPO had authorization, the OPO communicated to OR staff that the case was not a DCD case because the patient had already been declared brain dead and began recovery prior to cardiac asystole. The OPO initially reported it did not perform a root cause analysis (RCA). As a corrective action, FLMP stated it would no longer recover brain dead (BD) patients as DCD donors, explaining its

[REDACTED]
[REDACTED]
[REDACTED]
Life Alliance Organ Recovery Agency
March 12, 2020
Page 2

CONFIDENTIAL MEDICAL PEER REVIEW

position that if a family “will not authorize BD donation, the team will thank the family and shut down the case.”

The MPSC reviewed this case at its July 2019 meeting and requested an informal discussion with the OPO. The Committee was concerned by the lack of a root cause analysis and the decision to no longer permit brain dead patients to be DCD donors, which could result in fewer donated organs for transplant.

The informal discussion occurred on September 25, 2019, and included OPO staff who were involved in the case, OPO leadership, and an ad hoc subcommittee of the MPSC. The subcommittee was 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 DCD recovery. The subcommittee was also concerned by the OPO’s decision to proceed with organ recovery prior to asystole in this case. After the informal discussion, the reviewers requested the OPO conduct a formal RCA of this case; review its policies regarding DCD recoveries for brain-dead donors and compare them to industry standards; develop a protocol for management of DCD donors when the family wants to be present at withdrawal of care; review and consider revising its internal policies for when an RCA should be conducted; and train staff on any resulting policy or procedure changes.

The OPO submitted its response on October 14, 2019. As requested, FLMP conducted an RCA, 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. As a result of the RCA, FLMP concluded their original assessment that the cause of this event was the fragile emotional state of the donor’s mother was correct. FLMP also created an Authorization Addendum for BD as DCD Donation form, and in these cases will have the authorizing individual sign and acknowledge both types of donation, DCD and BD, on the Authorization for the Donation of Organs/Tissues form.

The MPSC reviewed FLMP’s submission at its meeting on November 7, 2019. The Committee was concerned about FLMP’s continued assertion that the root cause of this issue was the emotional state of the donor’s mother. 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 staff’s trust in the donation process and transplant system. The MPSC acknowledged that FLMP was motivated by a desire to recover the organs as quickly as possible, but appears to have prioritized speed of recovery over appropriate recovery procedures. The MPSC believed FLMP’s actions and response to this issue represented a fundamental risk to the public trust in and integrity of the transplant system and did not represent the standard of practice within the OPO community.

In addition, the MPSC believed FLMP’s RCA policies and procedures were unclear and needed significant improvement, and that these unclear policies may have caused a lack of understanding of the process gaps and breakdowns that precipitated this event. The MPSC was concerned FLMP may have significant issues with its quality systems, and believed it was important to review FLMP’s current quality systems to determine the potential scope of the issue and identify appropriate improvements.

[REDACTED]
[REDACTED]
Life Alliance Organ Recovery Agency
March 12, 2020
Page 3

CONFIDENTIAL MEDICAL PEER REVIEW

FLMP participated in an in-person interview on February 26, 2020. The MPSC considered FLMP's file, statements by the hospital's representatives, written records, and applicable provisions of the OPTN Final Rule, Bylaws and Policies. The MPSC also considered any supporting rationale, and generally accepted technical or scientific information that was relevant to the interview. UNOS staff will send a summary of the interview separately.

The MPSC appreciated FLMP's presentation, but still has concerns regarding the OPO's Quality Assurance and Performance Improvement (QAPI) program and its culture and leadership. The committee was also concerned by FLMP's decision to re-approach the donor's mother after the recovery to gain documentation of authorization for brain-death recovery, and believed this may have caused additional, unnecessary emotional injury to the donor family.

Based on its review, the MPSC approved the following:

RESOLVED, that the Membership and Professional Standards Committee issues a Letter of Warning to Life Alliance Organ Recovery Agency for violation of Policy 2.15.H (Organ Recovery).

FURTHER RESOLVED, that FLMP submit the following:

- Most recent Quality Assurance and Performance Improvement (QAPI) plan;
- Most recent QAPI metrics;
- Examples of recent RCAs FLMP has conducted; and
- QAPI meeting minutes.

The Committee voted 29 For, 2 Against, and 0 Abstentions.

FLMP should submit the requested information to Anne McPherson by 5 PM EDT on **June 1, 2020**, via secure email at [REDACTED] or at the address in the letterhead using a method that can be tracked and provides proof of receipt.

Pursuant to the above resolution, the MPSC hereby issues this Letter of Warning to FLMP. Please note, a Letter of Warning is defined in Appendix L of the Bylaws, which is accessible at <http://optn.transplant.hrsa.gov>. A Letter of Warning is not an adverse action under the Bylaws but is meant to inform the member of the need to ensure continuing compliance with policies. A Letter of Warning does not need approval from the Board of Directors, and is not made public. UNOS Member Quality staff will include the letter in your member compliance history, and it may be considered by the MPSC should future compliance issues arise.

For FLMP's reference, the MPSC is also providing the enclosed policy interpretation document regarding DCD recoveries after a brain death.

[REDACTED]
[REDACTED]
[REDACTED]
Life Alliance Organ Recovery Agency
March 12, 2020
Page 4

CONFIDENTIAL MEDICAL PEER REVIEW

You are reminded that this letter and all related documents comprise confidential medical peer review materials, which must be kept confidential by members during the review process and after the matter is closed. If you have any questions or concerns, or need any additional information regarding this resolution, please contact [REDACTED]

Sincerely,

[REDACTED]
[REDACTED]
Vice Chair, OPTN Membership and Professional Standards Committee

[REDACTED]
Enclosure

[REDACTED]
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[REDACTED]
Life Alliance Organ Recovery Agency
March 12, 2020
Page 5

CONFIDENTIAL MEDICAL PEER REVIEW

Policy Interpretation Regarding DCD Recoveries after a Brain Death

OPTN policies permit a DCD recovery to proceed after a brain death has been declared, provided the recovery complies with DCD protocol. Policy 2.15 states that DCD organ recovery process may occur following death by irreversible cessation of circulatory and respiratory functions. Though a declaration of brain death may have preceded such cessation of functions, the authorization for DCD recovery, for the purposes of compliance with OPTN policies, is not impacted by such a declaration. The issue of legal death, which varies among state laws, is a separate issue from compliance with OPTN policies and does not determine the policy interpretation in this scenario.

Also, per Policy 2.15.I, if a DCD donor converts to brain death, the OPO may choose not to reallocate based on brain death if the donor family does not approve and authorize. This provision contemplates a situation in which a potential donor is declared brain dead, but the family wishes to wait until circulatory arrest has occurred to proceed with donation and allows the OPO to honor such wishes.

While the lack of specific authorization to proceed with a DCD recovery following declaration of brain death is not explicitly stated in OPTN policies, it is also not specifically prohibited. In the context of compliance with OPTN policies, OPTN policy allows for determination of circulatory death after brain death has been declared, which therefore allows for DCD recovery to proceed after declaration of brain death as long as OPTN policies regarding DCD recovery, including consent and adhering to the hospital's DCD protocols, are followed.