



CONFIDENTIAL MEDICAL PEER REVIEW

August 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]

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). On July 22, 2020, the MPSC reviewed FLMP's latest submission.

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 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. 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

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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. Based on its review, the MPSC considered recommending the adverse action of Probation for FLMP.

FLMP participated in an in-person interview on February 26, 2020. The MPSC appreciated FLMP's presentation, but still had 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. In addition to issuing a Letter of Warning to FLMP, the MPSC requested 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.

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FLMP submitted the requested documentation on June 1, 2020, and the MPSC reviewed it during their meeting on July 22, 2020. The MPSC is still concerned about the culture at FLMP, noting that in one of the example root cause analyses the OPO submitted, staff still seemed uncomfortable stopping a verification process to identify an error. The Committee observed FLMP's QAPI meetings appear focused on reporting of issues, not performance improvement. In addition, the MPSC appreciates that FLMP consulted outside sources in developing its QAPI plan, but recommends the OPO tailor the plan to address the OPO's specific needs. FLMP should also modify its QAPI metrics so they are easier to understand and interpret. The MPSC concluded that it should continue to monitor FLMP to assist in quality improvement.

Based on its review, the MPSC approved the following recommendation:

RESOLVED, that Life Alliance Organ Recovery Agency participate in a peer visit.

The Committee voted 28 For; 1 Against and 2 Abstentions.

Peer Visit Information

Based on the MPSC's assessment of your OPO, the MPSC recommends FLMP undergo a peer conducted review. The review will provide an objective evaluation of the OPO by experienced transplant professionals. The process for the peer review is detailed in the member guide attached to this letter, but key aspects include:

- Given current travel limitations related to the COVID-19 pandemic, the peer review may be conducted via online video conference or held until a more appropriate date.
- The peer review panel will be selected from the transplant community and approved by either the MPSC Chair or Vice Chair. To avoid conflict of interest, no one affiliated (either through training or previous employment) with FLMP will be selected.
- The peer review panel are retained by the MPSC and no contact can occur between the peers and FLMP outside of the on-site peer visit until after the MPSC's review, including any due process to which FLMP may be entitled, is completed.
- UNOS staff will coordinate the arrangements with FLMP relative to prospective dates and an agenda.
- The expenses relating to the peer visit, including but not limited to the travel, lodging, and honoraria for the peer review panel and accompanying UNOS staff member are charged to FLMP.
- The MPSC will send a report to the member notifying it of the results of the peer review.

UNOS staff will contact FLMP to schedule the dates to conduct the peer review and will make every attempt to allow adequate notice of dates for the 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].

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Sincerely,

[REDACTED]

Chair, OPTN Membership and Professional Standards Committee

[REDACTED]

Enclosure

MEMBER GUIDE: PEER VISITS

Please note these are general peer visit guidelines. Given current travel limitations related to the COVID-19 pandemic, FLMP's peer review may be conducted via online video conference.

The MPSC has recommended your OPO participate in a peer conducted review. The following information is provided to assist in preparation for this visit. In addition, UNOS staff are happy to provide any additional information or answer any questions.

WHAT IS A PEER VISIT?

Peer visits are a tool used by the MPSC to obtain an objective evaluation of the OPO by experienced transplant professionals. Peer visits are conducted on behalf of the MPSC and under confidential medical peer review.

The peers will review the OPO's policies and procedures and information associated with the MPSC's review of the issue prior to the on-site visit. During the visit, the peers will conduct interviews and may tour the OPO's facilities. After the visit, the peer team will prepare a report outlining the OPO's strengths and opportunities for improvement. The MPSC will review and approve the report, and will ask the member to prepare a plan for quality improvement that addresses the team's findings.

WHO PARTICIPATES IN THE PEER VISIT?

The MPSC determines which types of OPO professionals should participate in the visit. UNOS staff identify potential peer team members and present recommendations to the MPSC Chair for approval. Peer teams typically include a CEO, COO, Quality Director, and may also include other professionals such as a Clinical Director, Family Services Expert or a CMO. At least one UNOS staff member will be on-site to help facilitate the visit.

The team will likely schedule interviews with the OPO Medical Director, possibly the OPO Board of Directors, and Medical Advisory Board. It is essential that key personnel are available during the visit.

WHEN WILL THE PEER VISIT TAKE PLACE?

UNOS staff will contact you shortly after you receive this letter to begin planning the visit. Peer teams are typically on-site for two days, and visits are typically held Tuesday – Wednesday or Wednesday – Thursday.

UNOS staff will make every effort to provide at least one month's advance notice of the visit and to work with the OPO to find dates that are mutually agreeable. If mutually agreed upon dates are not available, UNOS will make the final decision.

HOW SHOULD WE PREPARE FOR THE PEER VISIT?

- Review the OPTN/UNOS Policies and Bylaws referenced in the enclosed MPSC letter. OPTN Policies and Bylaws are available online at <https://optn.transplant.hrsa.gov/governance>.

- Provide all information requested by the MPSC in the enclosed letter by the specified due date. The peer team may identify additional information that will help them prepare for peer visit. UNOS staff will communicate any additional requests for information.
- Assign a designated contact to work with UNOS staff to plan the visit. Provide UNOS staff with the designated contact's name, email, office and cell phone numbers as soon as possible. The designated contact should:
 - Ensure key OPO personnel are available during the peer visit.
 - Work with UNOS staff to finalize the agenda.
 - Work with UNOS staff to arrange the peer team's lodging.
 - Work with UNOS staff to arrange the peer team's travel between the hotel and OPO during the visit and between the OPO and the airport/train station after the visit. (UNOS staff will arrange the peer team's air/train travel.)
 - Reserve a conference room large enough to accommodate the peer team, UNOS staff, and the largest group of interviewees for the duration of the visit. The room should have WiFi access and sufficient power outlets for the team's laptops.
 - Arrange for a light breakfast and lunch for the peer team in the conference room on both days of the visit.
 - If requested, ensure any requested donor records or other documents are in the conference room prior to the peer team's arrival.

WHAT SHOULD WE DO/EXPECT DURING THE PEER VISIT?

- The primary contact should greet the team upon their arrival to the OPO on the first day.
- Have a contact person near the conference room or easily accessible to answer questions or provide assistance as needed throughout the visit.
- Have an OPO staff person available to quickly address any IT issues or help in providing access to electronic medical records if needed.
- Be prepared to quickly provide any additional information the peer team may request, such as donor records, protocols or policies, and QAPI meeting minutes.
- UNOS staff will make every effort to stick to the schedule but may need to adjust the schedule to accommodate the peer team's requests. For example, the peer team may cancel a scheduled interview if they feel it is not necessary based on earlier interviews or documentation they reviewed. Alternatively, the team may request that an interviewee return to answer additional questions, or may ask to spend additional time reviewing donor records.
- Expect the peer team to ask direct and probing questions. Such questions are necessary in order for the peer team to obtain the necessary information as quickly as possible. All inquiries are intended to help the OPO, the peer team, and the MPSC identify potential areas for improvement.
- On the second day, after the last interview, the team will begin to draft their report based on their findings.
- The peer team will not conduct an exit interview or provide any information regarding their findings while on site. UNOS staff will answer any questions regarding next steps while on-site.

WHAT HAPPENS AFTER THE PEER VISIT?

- The peer team will finalize its report and will submit the report to the MPSC for review and approval.
- Peer team members are not permitted to interact with the OPO until the MPSC's review is complete. Please direct any questions or concerns to UNOS staff. Do not attempt to contact the peer team.
- UNOS staff will provide the OPO with a copy of the final report and any additional MPSC requests or recommendations. Staff will work with the MPSC to provide this information to the OPO as quickly as possible, but the timing is dependent on the MPSC meeting schedule and agendas. Staff will provide an estimated timeline for your receipt of the report after the peer visit.
- The MPSC will request that the OPO submit a plan for quality improvement that addresses all of the recommendations within the report. The MPSC typically requests that the OPO submit a response plan within 4 weeks, though actual due dates may vary based on the MPSC's meeting cycles.
- As a part of UNOS' continuous improvement efforts, staff will send you a survey regarding the peer visit process shortly after you receive the peer report. UNOS will also send you a survey approximately six months after the visit to assess the visit's impact on your OPO. Participation in the survey is completely optional, but we appreciate any feedback you are willing to provide and will use the information to identify areas for improvement in future peer visits.
- Expenses relating to the peer visit, including but not limited to travel and lodging for the peer team and at least one staff member and honoraria for the peer team, are charged to the OPO.